STATE OF LOUISIANA

VERSUS NO. 625543

PFIZER, INC.

STATE OF LOUISIANA

PARISH OF EAST BATON ROUGE

19TH JUDICIAL DISTRICT

SEC. 24

STATE
OCT 21 2013
BY
DEPUTY CLERK OF COURT

PETITION FOR DAMAGES AND JURY DEMAND

NOW INTO COURT comes Plaintiff, the State of Louisiana, by and through its Attorney General, James D. "Buddy" Caldwell, (hereinafter the "State"), submits this Petition against Pfizer, Inc. ("Defendant") and upon information and belief avers as follows:

I. INTRODUCTION

1. The Defendant has engaged in false, misleading, unfair, and deceptive acts in the marketing, promotion, and sale of its antidepressant drug, Zoloft (known generically as sertraline). The Defendant's fraudulent scheme has affected the elderly, disabled, and most needy Louisiana citizens covered by the State's Medicaid program, by causing numerous fraudulent and deceptive claims to be submitted to and reimbursed by the State. The Defendant caused thousands of false and deceptive claims to be made to the State by manipulating published efficacy data, paying key opinion leaders to bolster Zoloft's efficacy, and deceptively concealing Zoloft's inefficacy to physicians, customers, and the State.

2. Each year Louisiana spends hundreds of millions of dollars on prescription drugs under the Louisiana Medicaid program. In the past year alone, Louisiana Medicaid spent approximately $974 million on prescription drugs. Expenditures by the State for prescription drug reimbursements have increased exponentially in the past several years. This increase in prescription drug costs in recent years has contributed to a health care funding crisis within the State that requires action to ensure fair dealing between the Defendant and the State.

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3. The State is accountable to its citizens and taxpayers for how it spends limited State resources, and it is obligated to pursue any party whose unlawful conduct has led to the overspending of State funds. Consequently, the State, by and through its Attorney General, brings this action to recover amounts paid for the Defendant's ineffective drug by Louisiana Medicaid as a result of the fraudulent and deceptive conduct of the Defendant. The State further seeks to require the Defendant to account for and disgorge all profits obtained by the Defendant as a result of its improper and unlawful actions.

4. This lawsuit seeks legal and equitable redress for the fraudulent and wanton marketing, selling and labeling conduct of the Defendant, who has profited from its wrongful acts and practices at the expense of the State.

II. PARTIES

5. This action is brought for and on behalf of the sovereign State of Louisiana, by and through its duly elected and current Attorney General, James D. "Buddy" Caldwell. The Attorney General of the State of Louisiana, as chief legal officer of the State, is statutorily authorized to initiate and prosecute any and all suits deemed necessary for the protection of the interests and rights of the State under Article 4, Section 5 of the Louisiana Constitution of 1974 and pursuant to La. R.S. §§ 13:5036, 46:437.2, 46:438.1, 51:1407, 51:1408 and related statutes.

6. The Defendant, Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017. At all times relevant to this action, Pfizer engaged in the business of manufacturing, distributing, labeling, marketing, and/or selling Zoloft, among other pharmaceuticals, the cost of which is reimbursed by state Medicaid agencies nationwide, including Louisiana Medicaid.

III. JURISDICTION AND VENUE

7. This Court has jurisdiction over the State's claims as they involve claims arising exclusively under Louisiana law.

8. The State of Louisiana asserts no claims governed by Federal statutory law or Federal common law, as all claims asserted herein are exclusively state law claims for relief. The State of Louisiana makes no claims that would give rise to federal jurisdiction, nor does the alignment of the named parties create federal jurisdiction.

9. This Court has personal jurisdiction over the Defendant pursuant to La. C.C.P. Art. 6, La. R.S. §§ 13:3201, 51:1407(a), 51:1418 and related statutes because the Defendant engages in consumer transactions within the State of Louisiana, purposefully directs and/or directed its actions toward the State of Louisiana, and/or has the requisite minimum contacts with the State of Louisiana necessary to permit the Court to exercise jurisdiction.

10. Venue is proper in this judicial district pursuant to the Louisiana Code of Civil Procedure; La. R.S. §§ 46:437.8, 46:438.5(B)(4), 51:1407 and related statutes. Further, the State pays reimbursement through its Medicaid agency for drugs dispensed in this Parish and

throughout the State. The events giving rise to the claims herein arose, in substantial part, in this Parish.

IV. STATEMENT OF THE FACTS

11. The Louisiana Medicaid program is a state-administered program with federal matching funds that pays for medical care, including prescription drug benefits, for Louisiana's low-income and disabled citizens. Louisiana Medicaid currently covers approximately 1,360,000 individuals. Prescription drug benefits represent approximately 17% of Louisiana Medicaid's annual budget. The total annual cost of prescription drugs to Louisiana Medicaid continues to increase exponentially. Today, the total annual costs are approximately $974 million.

12. Louisiana Medicaid reimburses medical providers for drugs, including Zoloft, prescribed for, and dispensed to, Louisiana Medicaid recipients.

a. Zoloft Introduction

13. Zoloft (known generically as sertraline) is a selective serotonin reuptake inhibitor ("SSRI") that Pfizer markets as a treatment for depression. Theories suggest that depression is caused by low levels of serotonin in the brain. These theories further suggest that SSRIs can be used to increase the level of serotonin in the brain and thus, allegedly treat the primary cause of depression. Even though no actual evidence has been found to prove this theory, Pfizer uses this theory to promote the sale of Zoloft.

14. Zoloft development began in the early 1970s when Pfizer chemist, Reinhard Sarges, invented a new series of psychoactive compounds based on the structures of two antipsychotic drugs, thiothixene and chlorprothixene. Sarges eventually developed tametraline, a weak dopamine reuptake inhibitor; however, his efforts halted upon observing undesired effects in animals.

15. Several years later, in 1977, pharmacologist Kenneth Koe and Pfizer chemist Willard Welch began working with the tametraline compounds and eventually discovered a serotonin reuptake inhibitor. Koe and Welch tested the compound with animal behavioral scientist, Albert Weissman, and the compound was ultimately named sertraline.

16. Sertraline underwent clinical trials for the treatment of depression, and in 1991, the U.S. Food and Drug Administration ("FDA") hesitantly approved sertraline for the treatment of major depressive disorder ("MDD"). Pfizer released the drug that same year under the brand

name Zoloft. Zoloft eventually gained further approval for the treatment of panic disorder, post-traumatic stress disorder, obsessive-compulsive disorder, premenstrual dysphoric disorder, and social anxiety disorder.

b. New Drug Approval Process

17. In order to gain FDA approval for a new drug, a company must first perform laboratory and animal testing to discover whether the drug is likely to be safe and effective in humans. If the drug is deemed relatively safe, the company files an Investigational New Drug Application with the Center for Drug Evaluation and Research. A series of clinical trials on humans begins to determine whether the new drug or compound is safe and whether it is effective. The clinical trials occur in three different phases with each subsequent phase increasing the number of test subjects. The phases are designed to test the safety and efficacy of the drug for specific indications.

18. After completing the clinical trials, a company then files a New Drug Application ("NDA") containing all animal and human data, analyses of the data, information about how the drug behaves in the body, and information about how the drug is manufactured. When the FDA receives a complete application, it assigns the application to the appropriate therapeutic review division. A team of primary and secondary reviewers assesses the NDA and may make a recommendation to the FDA on the action to be taken with respect to the drug. The FDA may also convene an advisory committee to review the application and make a recommendation on the drug.

19. The FDA can approve the drug to be marketed in the United States, choose not to approve the drug, or label the drug "approvable" which allows the drug to be approved once problems in the application are addressed. Upon making a decision, the FDA then notifies the drug's sponsor.

20. For approval, the FDA requires only two (2) controlled clinical trials that produce statistically significant efficacy results, even if every other trial produced negative efficacy results. A statistically significant result means that the observed effect was not the result of chance while clinical significance means that the use of the drug over the placebo is meaningful enough to make a difference in the patient. The clinical significance of the drug-to-placebo differences is not assessed, and the number of total trials can vary greatly.

c. Pfizer Knew Zoloft Was Ineffective

21. Long before Zoloft was ever introduced to the market, Pfizer knew it had serious issues with inefficacy. In fact, in early Zoloft trials, the placebo group (those taking a sugar pill as opposed to Zoloft) actually had the most beneficial results. These early trials showed that "placebo still seems to be the most effective group" and that "there is still no striking evidence of beneficial drug effect with placebo often being the superior treatment." Nonetheless, Pfizer chose to go forward in attempting FDA approval.

22. Pfizer knew that the primary "benefit" from taking Zoloft was actually due to the placebo effect. The placebo effect is an improvement that has nothing to do with the actual efficacy of the medication, rather it is attributable only to the patient's belief that the drug is working. The placebo effect is controlled for in clinical trials by dividing individuals into two groups: a group taking the placebo (sugar pill) and a group taking the actual medication. The individuals, however, are unaware of their group. These placebo-controlled studies are used to assess the efficacy of the medication. If both groups receive the same benefit, then the benefit is due to the placebo effect, as opposed to the actual efficacy of the medication.

23. In 1990, Pfizer submitted its New Drug Application ("NDA") to the FDA with six (6) placebo-controlled trials. Of those six (6) trials, the majority showed that Zoloft was no more effective than the placebo in treating depression while only two (2) suggested that Zoloft had a minor positive impact.

24. However, the two (2) trials that suggested a minor positive impact as a result of taking Zoloft were flawed. In the first trial, during the first four weeks of treatment, Zoloft failed to produce a significant difference in the patients based on the Hamilton Rating Scale for Depression ("HAM-D"). After six weeks of treatment, patients taking 50mg of Zoloft experienced a slight improvement on the HAM-D, while patients taking 100mg and 200mg experienced no significant improvement. Moreover, 50% of the patients quit before the trial was completed.

25. In the second trial—which studied patients taking Zoloft, patients taking another anti-depressant, and patients taking a placebo—the results showed minimal improvements on the HAM-D in patients taking Zoloft versus those taking the placebo. In fact, during the first six weeks of this trial, patients showed no significant difference between the drug and the placebo. Like the first study, almost half of the participants quit before the trial was completed.

26. The FDA ultimately approved Zoloft, but not without reservation. The Psychopharmacological Drugs Advisory Committee expressed concern over Zoloft's efficacy, or lack thereof:

> However, it is difficult to determine the clinical significance of the statistically significant differences in mean change scores, particularly when you are looking at differences in a change of only 2 or 3 points on the HAM-D total scores...which is not a tremendous difference.[1]
>
> ...
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> So the question is how do we interpret these two positive results in the context of several more studies that fail to demonstrate that effect?...That would mean, in a sense, that [Pfizer] could just do studies until the cows come home until he gets two of them that are actually statistically significant by chance alone, walks them out and says he has met the criteria.[2]

27. Even Pfizer employees found it strange that the FDA did not ultimately question Pfizer regarding Zoloft's inefficacy. A Pfizer employee stated in an email, "I find it odd that FDA not at all questioning efficacy [sic] and there are significant questions raised by several European companies."

28. Pfizer also sought approval for Zoloft in numerous other countries; however, Pfizer's documents show that it knew other countries had serious efficacy concerns. A 1991 Pfizer memorandum indicates that sertraline "has received an unfavorable review in a number of countries. The common key issue is that the regulators are not convinced of sertraline efficacy versus placebo." In discussing studies to address this concern, the memorandum goes on to state that "preliminary analyses of these studies strongly indicated that they are not highly convincing of sertraline efficacy versus placebo" and that there "is considerable concern that these studies will not be convincing enough to gain approval." As a result, Pfizer sought to create a "strongly positive, placebo controlled study...to ensure regulatory success."

29. A December 1992 Pfizer memorandum shows that sertraline still "shows no trend to be better than placebo." It further states that even if sertraline did eventually show a trend of being better than the placebo, "it will not achieve statistical significance."

30. Additionally, numerous studies and clinical trials have indicated that Zoloft is ineffective. For example, a report analyzing data submitted to the FDA for the six (6) most widely prescribed antidepressants, including Zoloft, showed that almost an overwhelming 80%

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[1] Transcript of Psychopharmacological Drugs Advisory Committee Meeting at 48 (Nov. 19, 1990).
[2] *Id.* at 90-91.

of the response to the medications was duplicated in the placebo control groups.[3] A similar study again showed an exceptionally large response to the placebo and concluded that the overall effect of these antidepressants was well below the recommended criteria for clinical significance.[4] Furthermore, a 2010 study explained, "there is little evidence to suggest that [these drugs] produce specific pharmacological benefit for the majority of patients" for whom they are prescribed.[5] This latter study also explained the deceptive nature of the clinical trials stating, "There is little mention of the fact that efficacy data often come from studies that *exclude precisely those...patients who derive little specific pharmacological benefit from taking medications.*" (emphasis added.)[6]

31. Furthermore, in 2003, the Medicines and Healthcare Products Regulatory Agency ("MHRA") responsible for regulating all medicines in Great Britain also published data regarding the inefficacy of sertraline in adolescents that specifically stated the two controlled clinical trials "did not demonstrate efficacy."[7]

d. Pfizer Deceptively And Deliberately Concealed Zoloft's True Efficacy Information

32. Pfizer knew that Zoloft's efficacy was inadequate and at times nonexistent. Nonetheless, Pfizer fabricated an extensive scheme to mislead healthcare providers, and ultimately the State, about Zoloft's true efficacy. Pfizer withheld material efficacy information from the State, customers and healthcare providers in order to make a profit from the drug. Pfizer's unfair, unethical, fraudulent, immoral, and wanton conduct caused numerous Medicaid claims to be submitted based on this fabricated efficacy scheme.

33. Pfizer engaged and continues to engage in a deliberate, systematic practice of suppressing unfavorable results for its drug and misleading the State, healthcare providers, consumers, and policy makers about the actual efficacy of its drug.

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[3] Kirsch, Irving et al., *The Emperor's New Drugs: An Analysis of Antidepressant Medication Data Submitted to the U.S. Food and Drug Administration*, 5 Prevention & Treatment 23, 1-11 (2002).

[4] Kirsch, Irving et al., *Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration*, 5 PLOS Medicine 2 (Feb. 2008).

[5] Fournier, Jay C. et al., *Antidepressant Drug Effect and Depression Severity: A Patient-Level Meta-analysis*, 303 J. Am. Med. Assoc. 47-53, 47 (2010).

[6] *Id.*

[7] Medicines and Healthcare Product Regulatory Agency, *Selective Serotonin Reuptake Inhibitors (SSRIs): Overview of regulatory status and CSM advice relating to major depressive disorder (MDD) in children and adolescents including a summary of available safety and efficacy data, available at* http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON019494?useSecondary=&showpage=2 (last visited 7/17/2013).

Pfizer's Ghostwriting Scheme

34. Clinical research, and the peer-reviewed articles that are the result of that research, provide critical information to prescribing physicians and the general public. These articles provide information about the safety and efficacy of prescription medications and are commonly relied upon by physicians to provide timely updates and previously unknown data.[8]

35. Pfizer's fraudulent scheme includes a ghostwriting program to misleadingly enhance Zoloft's credibility.

36. "Ghost-writing" is a process where someone with a vested interest in an article, like Pfizer, that does not want their association with the article to be known, provides a written draft to an author who then publishes the article under that author's name. The published article contains no express or implied association with the interested person – Pfizer's involvement in drafting the article is unknown to the public. Not surprisingly, ghostwritten articles tout the benefits and efficacy of the drug in question.

37. Pfizer recognized that it could promote Zoloft and ensure the drug's success through manufacturing "research" and articles that enhance Zoloft's safety and credibility. Pfizer, or a communications company hired by Pfizer, would author a study and/or article specifically designed to enhance Zoloft's efficacy. Pfizer then paid prominent members of the medical field, known as "key opinion leaders," to put their name on the article and ultimately conceal all Pfizer involvement.

38. The most significant analysis of Pfizer's ghostwriting operation was done by Dr. David Healy, a professor at the University of Wales College of Medicine. Dr. Healy analyzed Zoloft articles coordinated by a medical writing agency known as Current Medical Directions ("CMD").[9] CMD coordinated more than eighty-five (85) journal articles about sertraline from 1998 to 2000. Fifty-five (55) of these articles were published, and every clinical trial offered results and analyses favorable to Pfizer. The CMD articles contained significant discrepancies between published data and the raw data from the actual clinical trials. Moreover, in a 1999 document prepared by CMD regarding Zoloft, several of the articles had already been written yet listed the author as "to be determined."

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[8] *See* Puneet Manchanda & Elizabeth Honka, *The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL'Y & ETHICS 785, 796 (2005).

[9] Healy, David; Cattell, Dinah, *Interface Between Authorship, Industry and Science in the Domain of Therapeutics*, 183 British J. of Psych. 22-27 (2003).

Pfizer's Selective Publication Of Efficacy Results

39. Pfizer's scheme further includes selective and biased publication of efficacy results. Pfizer selectively published clinical trials suggesting Zoloft's efficacy while suppressing actual negative efficacy results. Pfizer also published some negative studies yet misrepresented them as having a positive outcome. This selective publication "can lead to unrealistic estimates of drug effectiveness and alter the apparent risk-benefit ratio."[10]

40. A recent study unveiled this publication practice. In reviewing seventy-four (74) trials of antidepressants submitted to the FDA, researchers found that selective publication about efficacy resulted in biased conclusions about the effectiveness of antidepressant drugs.[11] In fact, 94% of publications reported successful results while the actual success rate was 51%. Furthermore, eleven (11) of the negative trials were actually published as having positive results. This selective reporting can "lead doctors to make inappropriate prescribing decisions that may not be in the best interest of their patients and thus, the public health." The study further revealed that Zoloft was the second to worst evaluated drug with 64% inflated efficacy.

41. Publication of clinical findings is the ultimate basis for most treatment decisions; thus, Pfizer's misleading publications regarding Zoloft efficacy are a key component of its fraudulent scheme. The New England Journal of Medicine, the Lancet, and the Journal of the American Medical Association expressed grave concern about the selective publication problem stating that "the current intellectual environment in which some clinical research is conceived, study subjects are recruited, and the data are analyzed and reported (or not reported) may threaten [the] precious objectivity."[12]

42. An internal Pfizer document demonstrates its ghostwriting and selective publication scheme in full effect. First, the document clearly reveals the intent to manipulate inefficacy results in a published manuscript:

> "...but now we need some help in dealing with the most important issue...i.e. the huge placebo response in the continuation phase which wiped out the significant superiority of ZOLOFT at six weeks."

The email goes on to list a number of ways to deal with the placebo response including "using less stringent criteria for relapse" and the suggestion that "Table III certainly must be deleted."

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[10] Turner, Erick H., et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 New Eng. J. Med., 252, 252-60 (2008).
[11] *Id.*
[12] *See* Editorial, *Sponsorship, Authorship, and Accountability*, 345 New Engl. J. Med. 825-27 (2001).

Lastly, the email requests " the list of French investigators identifying the *proposed authors*." (emphasis added).

43. Pfizer's ghostwriting operation and its selective publication of data, prevented healthcare providers, consumers, and ultimately the State of Louisiana from obtaining accurate information regarding the efficacy of Zoloft. Pfizer's scheme directly influenced the prescribing practices of healthcare providers through its misleading and inaccurate information bolstering Zoloft's efficacy.

Pfizer's Deceptive Advertising

44. Despite numerous studies that demonstrate that Zoloft is no more effective than a sugar pill at treating depression, Pfizer began widespread advertising efforts through various media outlets to promote Zoloft as an effective and dependable treatment for depression.

45. Pfizer's campaign efforts included a large sales force that visited prescribing healthcare professionals on a routine basis to actively promote Zoloft. Pfizer's sales force would incentivize the purchase of Zoloft by offering luxurious dinners and events, such as sporting events, trips, and entertainment. While offering such lavish incentives to the prescribing healthcare professionals, Pfizer's sales force would explain how effective Zoloft was at treating depression. Pfizer's sales force would leave free samples and various misleading literature designed to give the prescribing healthcare officials the impression that Zoloft was an effective and dependable treatment for depression.

46. Pfizer also focused on media advertisements aimed at prescribing healthcare professionals and consumers. Pfizer ran articles and cartoon depictions about Zoloft in medical journals and magazines, representing that Zoloft was very effective in treating depression and a prescription to Zoloft has "helped millions."

47. Additionally, Zoloft ran commercials depicting a cartoon character that Pfizer portrayed as being depressed. The commercial informed consumers that they no longer have to feel depressed anymore because Zoloft works to correct the chemical imbalance that causes their depression. Once Zoloft is introduced into the commercial, Pfizer then portrayed the cartoon character as happy, joyful, and no longer suffering from depression. Pfizer's advertisements were designed to convince consumers that Zoloft was very effective at treating depression, while omitting any information regarding known efficacy issues with the drug.

48. Pfizer further capitalized on the unproven theory that depression is linked to a decrease in levels of serotonin. Advertisements explained that Zoloft "fixes" the chemical imbalance that causes depression. An early Pfizer memorandum documenting a meeting with Dr. Stuart Montgomery reads that "Stuart Montgomery is convinced that anxiety and aggression are linked with serotonin...and this has 'tremendous marketing implications.'"

49. Pfizer's advertising to prescribing healthcare professionals and consumers excluded any information regarding the numerous clinical trials that showed Zoloft was no more effective than a sugar pill. Additionally, Pfizer further failed to disclose in its advertising that the two clinical trials purportedly showing Zoloft's efficacy showed only a minor effect of treating depression. Pfizer's media advertisements deliberately omitted this material information, thus misleading healthcare providers, consumers, and the State from making informed decisions regarding Zoloft. The advertisements Pfizer disseminated were untrue, deceptive and misleading.

V. CAUSES OF ACTION

a. Violations of the State's Unfair Trade Practices and Consumer Protection Law

50. The State hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Petition.

51. Defendant's deceptive and fraudulent marketing, selling and labeling of Zoloft as well as its scheme of misrepresenting efficacy results to the State, knowing that the State would ultimately reimburse for an ineffective drug, constitutes unfair and deceptive practices in violation of the State's Unfair Trade Practices and Consumer Protection Law, La. R.S. § 51:1401, *et seq.*

A. In the course of trade or commerce, Defendant intentionally, fraudulently, and deceitfully misrepresented the efficacy of its drug, for the purpose and with the intent to induce the State to pay for its ineffective drug in the form of Medicaid reimbursements, resulting in larger market share and/or profits for Defendant, in violation of La. R.S. § 51:1405.

B. Defendant knew or should have known that the State of Louisiana relied upon its efficacy disclosures in the purchasing and reimbursement of Zoloft. Therefore, there existed at all relevant times, a duty owed to the State and its

Medicaid agency, by Defendant, not to mislead the State when marketing, selling, and labeling its drug.

C. Defendant's unfair and deceptive practices, as outlined above, are immoral, unethical, oppressive and offensive to established public policy. Furthermore, Defendant's actions will continue to have a direct impact upon the public interest, as said actions and deceptive practices have potential for repetition.

D. As the actual and proximate result of Defendant's unfair and deceptive practices, the State has suffered actual damages by paying gross amounts for Defendant's ineffective drug.

E. In addition to actual damages pursuant to La. R.S. § 51:1408, the State is entitled to the civil penalties prescribed in La. R.S. § 51:1407 and related sections, since Defendant willfully engaged in unfair and deceptive acts and/or practices with the intent to defraud the State.

F. Finally, pursuant to La. R.S. § 51:1407, the State is entitled to a permanent injunction to restrain and enjoin Defendant from continuing to fraudulently and deceptively promote, in any way, the efficacy of Zoloft in violation of La. R.S. § 51:1405.

b. Violations of the State's Medical Assistance Programs Integrity Law

52. The State hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Petition.

53. Defendant's deceptive and fraudulent marketing, selling and promoting of Zoloft as well as its misrepresentation of efficacy results to the State for purposes of obtaining Medicaid reimbursements for providers in return for an increase in market share and profits, constitutes a violation of the State's Medical Assistance Programs Integrity Law, La. R.S. § 46:437.1, *et seq.*

A. By knowingly and willfully providing and/or publishing false efficacy information for its drug, knowing that the State, through its Medicaid program, purchases and/or reimburses for prescriptions written by physicians relying on efficacy results, Defendant unlawfully "present[ed] or cause[d] to be presented a false or fraudulent claim" for Medicaid benefits,

knowing the claim to be false, fictitious or fraudulent in violation of L.a. R.S. § 46:438.3(A).

B. By knowingly and willfully providing and/or publishing false efficacy information for its drug with knowledge that providers seek reimbursement from the State's Medicaid program for prescriptions written in reliance on such reports, Defendant unlawfully engaged in misrepresentation or made, used, or caused to be made or used "a false record or statement to obtain payment for a false or fraudulent claim" from the State's Medicaid fund in violation of L.a. R.S. § 46:438.3(B).

C. Defendant fraudulently concealed the true efficacy results of its drug from the State.

D. As the actual and proximate result of Defendant's violations of Louisiana's Medical Assistance Programs Integrity Law, as outlined above, the State has suffered actual damages by paying Medicaid reimbursements for the Defendant's ineffective drug.

E. In addition to actual damages, pursuant to La. R.S. § 46:438.6(A), the State is entitled to all civil penalties prescribed in La. R.S. § 46:438.6(B) and related sections, since Defendant has violated the State's prohibitions against fraudulent claims, as outlined above.

F. In addition to the actual damages provided in § 438.6(A) and the civil penalties imposed pursuant to § 438.6(B), Defendant shall further pay to the State all civil penalties provided in La. R.S. §§ 46:438.6(C)(1), 46:438.6(D) and related sections.

c. Fraud

54. The State hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Petition.

55. By knowingly and willfully providing, publishing, and/or causing to be published false and misleading information and by concealing and omitting material information concerning its drug to the State of Louisiana, the Defendant engaged and continues to engage in repeated fraudulent acts and practices, thus committing fraud against the State of Louisiana, pursuant to the Louisiana Civil Code, Articles 1953 and 2315.

A. Knowing that the State of Louisiana relies upon its reported efficacy information, there existed at all relevant times, a duty owed to the State by the Defendant, not to mislead the State when marketing, selling and labeling its drugs.

B. Defendant knowingly and intentionally made or caused to be made false and misleading statements and representations regarding the efficacy of Zoloft on a periodic and continuing basis, for publication and dissemination to the State of Louisiana.

C. Defendant made these false representations knowing they were false and/or with reckless disregard of their truth.

D. Defendant knew the false representations were to be used in the purchase and reimbursement of Zoloft and were; therefore, material.

E. Defendant fraudulently concealed the falsity and inaccuracy of the efficacy information from the State.

F. Defendant misrepresented the efficacy results of Zoloft with the intent to induce the State of Louisiana to rely on the false information in the purchasing and reimbursement of the drug, resulting in larger market share and/or profits for Defendant.

G. The State of Louisiana did not know the true efficacy results of Zoloft and had a right to rely on the representations made by Defendant.

H. The State of Louisiana reasonably relied upon the false information when reimbursing providers for purchasing and dispensing Zoloft.

I. As the actual and proximate result of Defendant's fraudulent conduct, and the State of Louisiana's reasonable reliance thereof, the State has paid substantial amounts in connection with purchases or reimbursements of Zoloft.

J. Defendant's misrepresentations are continuing, as the Zoloft label continues to present misleading information and conceals actual efficacy results.

K. The State is entitled to judgment against Defendant for the pecuniary loss it has suffered as a direct and proximate result of Defendant's fraudulent conduct.

d. Negligent Misrepresentation

56. The State hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Petition.

57. By providing, publishing, and/or causing to be published false information to the State of Louisiana, Defendant made and continues to make negligent misrepresentations to the State of Louisiana, pursuant to the Louisiana Civil Code, Article 2315.

A. There existed at all relevant times a legal duty owed to the State, by Defendant, to provide accurate information to the State in the marketing, selling and labeling of Zoloft.

B. Defendant breached its duty to provide accurate information to the State, by affirmatively providing false and misleading statements regarding the efficacy of Zoloft.

C. The State of Louisiana did not know the true efficacy information of Zoloft and had a right to rely on the representations made by Defendant.

D. The State of Louisiana reasonably relied upon the false information when reimbursing providers.

E. As an actual and proximate result of Defendant's misrepresentations, and the State of Louisiana's reasonable reliance thereof, the State has been damaged by paying substantial amounts in reimbursements for Zoloft.

F. The State is entitled to judgment against Defendant for restitution and civil penalties for the losses incurred by the State of Louisiana as a direct and proximate result of Defendant's misrepresentations.

e. Unjust Enrichment

58. The State hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Petition.

59. By knowingly concealing and manipulating the efficacy of its drug in order to make a profit, Defendant has been unjustly enriched.

A. Defendant's unlawful conduct, as outlined above, conferred a benefit upon Defendant in the form of increased profits.

B. Defendant has retained and continues to retain the benefits conferred upon it as a result of its unlawful conduct and to the detriment of the State of Louisiana.

C. Defendant's retention of such a benefit is unjust, as it was obtained by fraudulently withholding material information concerning the efficacy of its drug from the State with the knowledge that the State would rely on that information to its detriment.

f. Redhibition

60. The State hereby repeats, incorporates by reference and re-alleges each and every allegation set forth above in this Petition.

61. Defendant's drug, Zoloft, marketed in the State of Louisiana contains a vice or defect that renders it useless or its use so inconvenient that providers would not have purchased it, and providers would not have dispensed it, and thus the State of Louisiana would not have reimbursed for purchases.

A. Defendant sold Zoloft in the State of Louisiana. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. Louisiana Civil Code, Article 2520. Zoloft, sold or promoted by Defendant, possesses redhibitory defects because it was ineffective and fraudulently marketed. Zoloft is ineffective, which renders it useless or so inconvenient that it must be presumed that physicians would not have prescribed the drug, providers would not have requested the drug or filled prescriptions, and the State of Louisiana would not have reimbursed for purchases of the drug. Accordingly, rescission of the sales or reimbursements of Zoloft is proper.

B. In the alternative, Zoloft possesses redhibitory defects that diminished its values, so it must be presumed that physicians would have prescribed, patients would have requested, and providers would have filled prescriptions, and the State of Louisiana would have made reimbursements for a lesser price. In this instance, reduction of the prices or reimbursements of Zoloft is proper.

C. Defendant is liable as a bad-faith seller for selling or marketing a defective product with knowledge of the defects, and is thus liable for the prices or reimbursements of Zoloft, plus interest from the purchase or reimbursement dates, as well as reasonable expenses occasioned by the sales or promotions of the drug and attorneys' fees. As the manufacturers of the drug, under Louisiana law, Defendant is deemed to know that the drug possessed redhibitory defects.

VI. JURY DEMAND

Plaintiff hereby demands a trial by jury on all claims so triable pursuant to La. C.C.P. Art. 1731 and related statutes.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the State of Louisiana, by and through its Attorney General, James D. "Buddy" Caldwell, prays for relief as follows:

A. An award of actual damages to the State in such amount as is proven at trial, together with prejudgment interest;

B. All statutory fines, penalties, attorneys' fees and costs, pursuant to Louisiana's Unfair Trade Practices and Consumer Protection Law, Louisiana's Medical Assistance Programs Integrity Law, and related statutes.

C. A permanent injunction to restrain and enjoin the Defendant from committing further violations of Louisiana's Unfair Trade Practices and Consumer Protection Law under La. R.S. § 1407.

D. An accounting of all profits or gains derived in whole or in part by the Defendant through the misconduct complained of herein and disgorgement of all improper and ill-gotten profits;

E. Any other relief that is equitable under the law as may be proven at the trial.

Respectfully SUBMITTED and DATED this 21 day of Oct, 2013.

JAMES D. "BUDDY" CALDWELL
ATTORNEY GENERAL FOR
THE STATE OF LOUISIANA
JAMES D. "BUDDY" CALDWELL –NO. 02211
KEETSIE GUNNELS – NO. 12952

NICHOLAS J. DIEZ –NO. 31701
1885 North Third Street
Baton Rouge, Louisiana 70802
Telephone: (225) 326-6449
1885 North 3rd Street
Baton Rouge, Louisiana 70802

and

SHOWS, CALI & WALSH, LLP
E. WADE SHOWS – No. 7637
628 St. Louis Street
Baton Rouge, Louisiana 70802
Telephone: 225-346-1461
Facsimile: 225-346-1467

and

BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
W. DANIEL "DEE" MILES, III (*pro hac vice* pending)
C. LANCE GOULD (*pro hac vice* pending)
ALISON D. HAWTHORNE (*pro hac vice* pending)
272 Commerce Street
Post Office Box 4160 (36103)
Montgomery, Alabama 36104
Telephone: (334) 269-2343
Facsimile: (334) 954-7555

and

USRY, WEEKS & MATHEWS, APLC
T. ALLEN USRY – No. 12988
1615 Poydras Street, Suite 1250
New Orleans, Louisiana 70112
Telephone: 504-592-4600
Facsimile: 504-592-4641

and

JAMES E PAXTON, APLC
JAMES E. PAXTON — No. 19094
Post Office Box 97
St. Joseph, Louisiana 71366
Telephone: 318-766-4892
Facsimile: 318-766-3945

PLEASE SERVE:

PFIZER, INC.
Through its agent for service:
C T Corporation System
5615 Corporate Blvd., STE. 400B
Baton Rouge, LA 70808