

CAUSE NO. _____

THE STATE OF TEXAS,
Plaintiff

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IN THE DISTRICT COURT OF

VS.

DALLAS COUNTY, TEXAS,

PFIZER INC,
Defendant.

____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT

COMES NOW, THE STATE OF TEXAS, acting by and through Attorney General GREG ABBOTT (“State”), filing Plaintiff’s Original Petition complaining of and against Plaintiff, Pfizer Inc (“Defendant”) and would respectfully show the court the following:

AUTHORITY

1. This action is brought by Attorney General Greg Abbott, through his Consumer Protection Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by § 17.47 of the Texas Deceptive Trade Practices – Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41 et seq. (“DTPA”), upon the grounds that Defendant has engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§ 17.46(a) and (b) of the DTPA.

PARTY DEFENDANT

2. Defendant is Pfizer Inc, a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, NY 10017. At all relevant times, Pfizer did

business in Texas selling and promoting prescription drugs, including Zyvox® and Lyrica®. Pfizer may be served with process by serving its registered agent at CT Corp System, 350 North St. Paul Street, Dallas, Texas 75201.

VENUE

3. Venue for this action properly lies in Texas pursuant to § 17.47(b) of the DTPA because Defendants' acts and practices that violate these statutes occurred throughout Texas, including Dallas County, Texas.

PUBLIC INTEREST

4. Because Plaintiff State of Texas has reason to believe that Defendant has engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS had reason to believe that Defendant has caused and will cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

ACTS OF AGENTS

5. Whenever in this petition it is alleged Defendant did any act or thing, it is meant that Defendant performed or participated in such act or thing or that such act was performed by agents or employees of Defendant and in each instance, the agents or employees of Defendant were then authorized to and did in fact act on behalf of Defendant or otherwise acted under the guidance and direction of Defendant.

TRADE AND COMMERCE

6. Defendant has, at all times described below, engaged in conduct which constitutes “trade” and “commerce” as those terms are defined by § 17.45(6) of the DTPA.

NOTICE BEFORE SUIT

7. Plaintiff informed Defendant herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

Background

8. The Food and Drug Administration (“FDA”) approved Pfizer’s Zyvox® as an antibacterial agent to treat certain types of infections, including among other approved indications, nosocomial pneumonia caused by methicillin-resistant *Staphylococcus aureus* (“MRSA”) and complicated skin and skin structure infections due to MRSA.

9. Pfizer marketed Zyvox® as superior to vancomycin, an antibiotic that has been on the market for nearly fifty years and used in the treatment of infections caused by MRSA, although Zyvox® has not been demonstrated by substantial evidence to be superior to vancomycin for certain uses as Pfizer marketed.

10. Additionally, on July 20, 2005, the FDA sent a Warning Letter to Pfizer concerning a journal advertisement for Zyvox®. The FDA claimed that Pfizer’s advertisement misbranded Zyvox® by making misleading and unsubstantiated implied superiority claims that broadened the indications for Zyvox®.

11. Despite notifying its sales force to cease using the promotional material identified in the FDA Warning Letter, Pfizer did not provide adequate guidance to its sales force regarding what statements were permissible concerning data from head-to-

head trials and retrospective analyses and what promotional statements were not permitted.¹ As a result, Pfizer's sales personnel continued to make superiority claims that were inconsistent with the FDA's Warning Letter and the FDA approved label for Zyvox.®

12. Moreover, certain Pfizer sales managers, including a regional manager and a headquarters-based vice president, were aware of and, in certain cases, encouraged a sales message that Zyvox® was superior to vancomycin for certain patients, despite their knowledge of the FDA Warning Letter and the issues it raised.

13. In addition to Zyvox®, Pfizer marketed another of its drugs, Lyrica® for off-label uses. Lyrica® was approved by the FDA for the treatment of diabetic peripheral neuropathy (DPN), post-herpetic peripheral neuropathy (PHN) and for the adjunct treatment of partial seizures in December, 2004. Contrary to the approved intended uses, Pfizer marketed Lyrica® for the treatment of chronic pain, neuropathic pain (other than DPN and PHN), perioperative pain, and migraine. Subsequently, the FDA did approved Lyrica® for the treatment of fibromyalgia in June 22, 2007.

14. Pfizer also encouraged its sales force to promote Lyrica® as superior to another Pfizer drug, Neurontin, and its generic equivalent, gabapentin. Moreover Pfizer encouraged its sales force to encourage physicians to convert their patients from Neurontin to Lyrica® and motivated their sales force by sales incentive plans.

¹ At the FDA's request, Pfizer agreed to publish a corrective advertisement in February 2006, which was entitled "IMPORTANT CORRECTION OF DRUG INFORMATION ZYVOX." In this corrective advertisement, Pfizer noted that the FDA had objected to the presentation, in its previous advertisement, of clinical data that showed a more favorable comparison of Zyvox to vancomycin than was shown in the data included in the Zyvox label.

VIOLATIONS OF DTPA

15. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 14.

16. Defendant, in the course of marketing, promoting, selling, and distributing the prescription drugs Zyvox® and Lyrica®, have engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under § 17.46 (a) and (b) of the Texas Deceptive Trade Practices-Consumer Protection Act, including but not limited to representing that goods or services have characteristics or benefits that they do not have in violation of § 17.46(b)(5) of the DTPA by promoting Zyvox®, despite assuring FDA in response to its Warning Letter that it discontinued such promotion, and Lyrica® by claiming superiority of these drugs over other drugs without substantial evidence.

INJURY TO CONSUMERS

17. By means of the foregoing unlawful acts and practices which were producing causes of injury to the persons affected, Defendant has acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

CONTINUING VIOLATIONS

18. Defendant has violated and could continue to violate the laws as hereinabove alleged. Defendant, unless restrained by this Honorable Court, could continue to violate the laws of the State of Texas. Defendant has violated and could continue to violate the Deceptive Trade Practices-Consumer Protection Act.

PRAYER

19. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that:

A. Defendant be cited accorded to law to appear and answer herein and that upon final hearing, a PERMANENT INJUNCTION be issued restraining and enjoining Defendant and its the its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with it, from engaging in deceptive practices in the promotion and marketing of its pharmaceutical products;

B. Pursuant to § 17.47(c)(1) of the DTPA, the Defendant be ordered to pay civil penalties in the amount of not more than \$20,000.00 for each and every violation of the DTPA;

C. Pursuant to § 402.006(c) of the Tex. Gov't Code, the Defendant be ordered to pay costs and reasonable attorneys' fees incurred by the State in connection with the investigation and litigation of this matter; and

D. That the Court grant such further relief as the Court deems necessary or appropriate to remedy the effects of Defendant's unlawful trade practices.

Dated: December ____, 2012.

Respectfully submitted,

Plaintiff State of Texas

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