

CAUSE NO. 12-05053

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2012 MAY -7 AM 8:26
JOY FITZSIMMONS
DISTRICT CLERK
DALLAS CO., TEXAS
DEPUTY

THE STATE OF TEXAS,
Plaintiff,

VS.

ABBOTT LABORATORIES,
Defendant.

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IN THE DISTRICT COURT OF

DALLAS COUNTY, TEXAS,

←-192nd 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 Abbott Laboratories ("Defendant" or "Abbott") 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. §17.47 *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 c§17.46(a) and (b) of the DTPA.

PARTY DEFENDANTS

2. Defendant Abbott Laboratories, ("Abbott" or "Defendant"), is an Illinois corporation with its principal place of business at 100 Abbott Park Road, D-322 AP6D, Illinois, 60064. Defendant transacts business in Texas and nationwide by advertising, soliciting, selling, promoting and distributing prescription drugs, including, marketing, promoting, selling and distributing prescription drugs, Depakote®, to consumers in the State of Texas and nationwide.

VENUE

3. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA because Defendant's 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 has 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 at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made.

BACKGROUND

8. Drug companies are prohibited by the Food Drug and Cosmetic Act of 1938, 21 USCA § 321 *et seq* (“FDCA”) from promoting drugs for indications (uses) that are not approved by the U.S. Food and Drug Administration (“FDA”).

9. In order to obtain FDA approval to lawfully market a drug in the United States, a drug company must submit clinical trials that prove by substantial evidence that the drug is safe and effective for its intended use.

NATURE OF DEFENDANT’S CONDUCT

10. Abbott obtained FDA approval to market the prescription drug Depakote® (“Depakote”) only for treatment of seizure disorders, mania associated with bipolar disorder, and prophylaxis of migraines.

11. In addition to the indications approved by the FDA, Abbott knew that doctors prescribed Depakote “off-label” to treat a number of other indications, including agitation associated with dementia, and as combination therapy with antipsychotic medications to treat schizophrenia.

12. Although Abbott did not possess substantial evidence to substantiate a claim that Depakote is effective for the treatment of agitation associated with dementia, or as adjunct therapy with antipsychotics to treat schizophrenia, Abbott bypassed the regulatory process and engaged in off-label promotion for these indications.

13. The clinical studies required by the FDA to demonstrate safety and efficacy for these new indications would be expensive and the results of the required studies might not be sufficient to support Abbott's application.

14. Even if the FDA approved the new indications, the patent on Depakote would expire at about the same time as FDA's approval, and Abbott would not be able to take advantage of the approval before cheaper generics captured the market.

15. Abbott instructed its sales representatives to distribute and detail studies that found Depakote to be effective for the off-label uses. However, these studies were not competent and reliable scientific evidence, did not substantiate efficacy, and were not for the approved uses.

16. Abbott also promoted Depakote through Continuing Medical Education events which are supposed to be independent. In fact, these events were promotional in nature and an integral part of Abbott's scheme to promote for the off-label uses.

17. To support its efforts to promote Depakote for schizophrenia in combination with antipsychotic drugs to treat schizophrenia, Abbott conducted a clinical trial relating to this use. However, the result of this study was negative and showed the addition of Depakote to be ineffective. Nonetheless, Abbott continued to promote Depakote as an adjunct with antipsychotic medications to treat schizophrenia and failed to timely publish or publicize the negative study results.

18. Similarly, even after Abbott learned about a well conducted, well designed clinical trial that found Depakote to be ineffective for treatment of agitation associated with dementia, Abbott continued to promote Depakote off-label for this indication.

**VIOLATIONS OF TEXAS DECEPTIVE TRADE PRACTICES-CONSUMER
PROTECTION ACT**

19. Defendant, as set forth above, in the course and conduct of trade and commerce, has directly and indirectly engaged in false, misleading, and deceptive acts and practices declared unlawful by §17.46 (a) and (b) of the Texas Deceptive Trade Practices-Consumer Protection Act, including but not limited to:

- A. Causing confusion or misunderstanding as to the approval of the drug Depakote, in violation of § 17.46(b)(2) of the DTPA;
- B. Representing that the drug Depakote has benefits which it does not have, in violation of § 17.46(b)(5) of the DTPA;
- C. Representing that the drug Depakote is of a particular standard, quality, or grade, if it is of another, in violation of § 17.46(b)(7) of the DTPA; and
- D. Failing to disclose information about the drug Depakote, when such failure to disclose was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of § 17.46(b)(24) of the DTPA.

INJURY TO CONSUMERS

20. By means of the foregoing unlawful acts and practices, 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

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

PRAYER

22. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that Defendant be cited according to law to appear and answer herein and that upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendant and its agents, servants, employees, representatives, subsidiaries, divisions, successors, and assigns from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

- A. Causing confusion or misunderstanding as to the approval of the drug Depakote;
- B. Representing that Defendant's drug Depakote has benefits which it does not have;
- C. Representing that Defendant's drug Depakote is of a particular standard, quality, or grade, if it is of another; and
- D. Failing to disclose information, when such failure to disclose was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

25. The STATE OF TEXAS further prays, that upon final hearing, this Court order Defendant to pay civil penalties of not more than \$20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

26. The STATE OF TEXAS further prays that the Office of the Attorney General be awarded their investigative costs, court costs, reasonable attorneys' fees, expenses, and witness fees pursuant to the laws of the State of Texas including the TEX. GOV'T CODE ANN. §402.006(c).

27. The STATE OF TEXAS further prays that upon final hearing that this Court grants all other relief to which the State may be justly entitled.

Respectfully submitted,

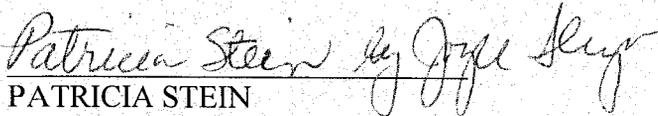
GREG ABBOTT
Attorney General of Texas

DANIEL T. HODGE
First Assistant Attorney General

JOHN SCOTT
Deputy Attorney General for Civil Litigation

TOMMY PRUD'HOMME
Chief, Consumer Protection Division

JOYCE WEIN ILIYA
Managing Attorney, Health Team

 Date: 5-4-12

PATRICIA STEIN
Assistant Attorney General
State Bar No. 24033222
Consumer Protection Division
1412 Main St., Ste. 810
Dallas, Texas 75202
(214) 969-7639, ext. 8816
(214) 969-7615 fax
Patricia.Stein@texasattorneygeneral.gov

Attorneys for the State