IN THE IOWA DISTRICT COURT OF POLK COUNTY

STATE OF IOWA, ex rel. THOMAS J. MILLER, ATTORNEY GENERAL OF IOWA 99AG25112 Plaintiff, vs. ABBOTT LABORATORIES Defendant.	)	EQUITY NO. 7/444 PETITION

The State of Iowa, ex rel. Attorney General Thomas J. Miller, by Assistant Attorney General Nathan Blake, files this Petition pursuant to the provisions of Iowa Code section 714.16(2)(a) (2011), commonly known as the Iowa Consumer Fraud Act, and in support of its claims states as follows:

PARTIES

1. Thomas J. Miller is the duly elected Attorney General of the State of Iowa.

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.

3. Abbott transacts business in the State of Iowa by advertising, soliciting, selling, promoting and distributing prescription drugs, including Depakote® ("Depakote"), to consumers in the State of Iowa and nationwide.

JURISDICTION AND VENUE

4. The Attorney General of Iowa has the authority to initiate an action for consumer fraud in violation of Iowa Code § 714.16.

5. This Court has jurisdiction over the Defendant pursuant to Iowa Code section 714.16, because the Defendant transacted business within the State of Iowa at all times relevant to this Petition.

6. Venue is proper in Polk County, pursuant to Iowa Code § 714.16(10), because the Defendant conducted business in Polk County, and one or more of the victims reside in Polk County.

FACTUAL ALLEGATIONS

7. Paragraphs 1 - 7 are incorporated herein by reference.

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.

10. Abbott obtained FDA approval to market the prescription drug 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 chose to bypass the regulatory process and to engage in off-label promotion for these indications.

13. The decision to promote Depakote off-label was driven by Abbott's understanding that the studies required by the FDA to demonstrate safety and efficacy for these indications would be expensive and the results of the required studies might not be sufficient to support Abbott's application.

14. Abbott was also concerned that 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 and did not substantiate efficacy.

16. Abbott also promoted Depakote at supposedly independent Continuing Medical Education events. In fact, these events were promotional in nature and an integral part of the 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.

19. Neither all nor any part of the application for injunctive relief herein has been presented to and refused by any court or justice. Iowa R. Civ. P. 1.1504.

20. In an action by the state, no security shall be required of the state. Iowa R. Civ. P. 1.207.

CAUSE OF ACTION

Consumer Fraud

21. The State realleges and incorporates each and every allegation contained in the preceding paragraphs 1 – 20.

22. In the course of advertising, soliciting, selling, promoting and distributing the prescription drug Depakote, Abbott has engaged in unlawful practices pursuant to Iowa Code section 714.16(2)(a) by representing that Depakote has certain performance characteristics, accessories, uses, or benefits while no reasonable basis for the claim existed.

REQUEST FOR RELIEF

WHEREFORE, the plaintiff prays that the Court enter an Order:

A. Issuing a permanent injunction pursuant to Iowa Code section 714.16(7), prohibiting Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in unfair or deceptive conduct;

B. Ordering Defendant to pay reasonable attorney fees and costs for the prosecution and investigation of this action, as provided by Iowa Code section 714.16(11);

C. Ordering Defendant to pay civil penalties of up to $40,000 for each violation of the Iowa Consumer Fraud Act pursuant to Iowa Code section 714.16(7); and

D. Granting such other and further relief as the Court deems equitable and proper.

DATED: May 7, 2012.

Respectfully submitted,

THOMAS J. MILLER
IOWA ATTORNEY GENERAL

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