STATE OF NORTH CAROLINA WAKE COUNTY	IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION	
	FILE NO.	M. Mar. C.
STATE OF NORTH CAROLINA, ex rel	l. ROY)	By Tool My
COOPER, ATTORNEY GENERAL,)	L'ACISCO S
Plaintiff,)))	
vs.) CO	OMPLAINT
ABBOTT LABORATORIES,))	
Defendant.)))	

Plaintiff State of North Carolina, by and through its Attorney General Roy Cooper, brings this action complaining of Defendant Abbott Laboratories for violations of North Carolina's Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1 et seq., as follows:

<u>PARTIES</u>

- 1. Plaintiff is the State of North Carolina acting on relation of its Attorney General, Roy Cooper, who brings this action pursuant to authority found in Chapters 75 and 114 of the North Carolina General Statutes. Plaintiff is charged, *inter alia*, with the enforcement of the Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, *et seq*.
- 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.

JURISDICTION AND VENUE

3. This Court has jurisdiction over Defendant pursuant to N.C. Gen. Stat. § 1-75.4 because Defendant has transacted business within the State of North Carolina at all times relevant to this

Complaint.

4. Venue for this action properly lies in Wake County, North Carolina pursuant to N.C. Gen. Stat. § 1-79 because Defendant transacts business in Wake County, North Carolina and/or some of the transactions out of which this action arose occurred in Wake County, North Carolina. Venue also properly lies in Wake County pursuant to the authority granted the Attorney General by N.C. Gen. Stat. § 75-14.

FACTUAL ALLEGATIONS

- 5. Defendant was at all times relative hereto engaged in trade or commerce in the State of North Carolina.
- 6. 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").
- 7. In order to obtain FDA approval to 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.
- 8. 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.
- 9. 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.
- 10. Although Abbott did not have FDA approval to market Depakote for the treatment of agitation associated with dementia or as adjunct therapy with antipsychotics to treat

schizophrenia, Abbott engaged in off-label promotion for these indications.

- 11. Abbott instructed its sales representatives to market Depakote for the off-label uses even though it did not possess sufficient clinical evidence to substantiate claims that Depakote was effective for such uses.
- 12. Abbott also promoted Depakote at Continuing Medical Education events, which are supposed to be independent. However, some of these events were promotional in nature and were part of Abbott's plan to promote for the off-label uses.
- 13. 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 did not show the addition of Depakote to be effective. Nonetheless, Abbott continued to promote Depakote as an adjunct with antipsychotic medications to treat schizophrenia and did not timely publish or publicize the study results.
- 14. Similarly, after Abbott learned about a 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.

CLAIM FOR RELIEF

UNFAIR AND DECEPTIVE TRADE PRACTICES

- 15. Plaintiff realleges and incorporates each and every allegation contained in the preceding paragraphs 1 through 14.
- 16. In the course of advertising, soliciting, selling, promoting and distributing the prescription drug Depakote, Abbott engaged in a course of trade or commerce that violates N.C.G.S. § 75-1.1 by representing that Depakote had characteristics, ingredients, uses, benefits, quantities or qualities that it did not have.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this honorable Court enter an order:

- A. Issuing a permanent injunction prohibiting Defendant, its agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with it, from engaging in unfair or deceptive conduct;
- B. Ordering Defendant to pay reasonable costs for the prosecution and investigation of this action; and
- C. Granting such other and further relief as the Court deems equitable and proper.This the 7th day of May, 2012.

ROY COOPER Attorney General

BY:

Creecy C. Johnson

Assistant Attorney General

114 W. Edenton St.

Raleigh, N.C. 27603 Tel. (919) 716-6032

Fax (919) 716-6050

ccjohnson@ncdoj.gov