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STATE OF VERMONT
OFFICE OF THE ATTORNEY GENERAL
109 STATE STREET
MONTPELIER, VT
05609-1001

May 7, 2012

Claire Mee, Clerk of Court
Washington Superior Court
65 State Street
Montpelier, VT 05602

Hand Delivered

Re: In re State of Vermont v. Abbot Laboratories

Dear Ms. Mee:

Enclosed for filing with the Court on the above-referenced matter, please find a Complaint for Injunctive and Other Relief. I would appreciate your returning the copy to me with your docket number and date stamp noted.

Thank you.

Sincerely yours,

A handwritten signature in black ink, appearing to be "JM" or similar initials.

Jessica Mishaan
Legal Assistant

Enc.

STATE OF VERMONT
SUPERIOR COURT
WASHINGTON UNIT

2012 JUL -7 P 3:25

STATE OF VERMONT

Plaintiff,

vs.

ABBOTT LABORATORIES

Defendants.

CIVIL DIVISION

Docket No. 363512Wncv

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

NOW COMES the Plaintiff, the State of Vermont, through William H. Sorrell Attorney General of the State of Vermont ("Plaintiff"), and brings this action against Defendant Abbott Laboratories ("Defendant" or "Abbott") and states the following upon information and belief:

JURISDICTION AND VENUE

1. Plaintiff brings this action pursuant to the provisions of the Vermont Consumer Fraud Act, 9 V.S.A §§ 2451-2466(the "Act").
2. This Court has jurisdiction over the Defendant pursuant to 9 V.S.A. § 2458(a), which provides that an action may be brought in the "superior court of the county in which such person resides, has a place of business or is doing business."
3. Venue for this action properly lies in Washington County pursuant to 9 V.S.A. § 2458(a).

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PARTIES

4. Plaintiff is charged, *inter alia*, with the enforcement of the Vermont Consumer Fraud Act, 9 V.S.A §§ 2451-2466.

5. Defendant is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott advertises, solicits, sells, promotes and distributes drugs, including the prescription drug Depakote® (“Depakote”), in the State of Vermont and nationwide.

BACKGROUND

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

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

8. Abbott obtained FDA approval to market Depakote only for the 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 possess sufficient evidence to substantiate a claim that Depakote was effective for the treatment of agitation associated with dementia, or as adjunct

therapy with antipsychotics to treat schizophrenia, Abbott made a conscious decision (in the 1998 to 1999 time frame with respect to the treatment of agitation associated with dementia, and in 2001 with respect to its use as adjunct therapy with antipsychotics to treat schizophrenia) to bypass the regulatory process and to engage in off-label promotion for these indications.

11. The decision to promote Depakote for off-label use 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 that the results of the required studies might not be sufficient to support Abbott's application.

12. Timing was also an issue. Abbott was concerned that even if the FDA did approve the new indications before the 2006 expiration of the patent for Depakote (and Abbott did not know if there would be sufficient evidence to approve a new indication for schizophrenia or whether the FDA would approve it), Abbott would not receive approval, or be able to take advantage of the approval, before cheaper generics captured the market.

13. Abbott presented Depakote for off-label use at purportedly independent Continuing Medical Education events during the 1998-1999 time period, and in 2003, with respect to the treatment of agitation associated with Dementia, and as adjunct therapy with antipsychotics to treat schizophrenia, respectively. In fact, however, these events were promotional in nature and an integral part of Abbott's scheme to improperly promote Depakote for off-label uses.

14. After 2001, Abbott conducted a clinical trial to support its efforts to promote Depakote, in combination with antipsychotic drugs, to treat schizophrenia. However, the result of this study was negative. In fact, it showed that the addition of Depakote was

ineffective. Nonetheless, Abbott continued to promote Depakote as an adjunct to antipsychotic medications for the treatment of schizophrenia, but failed to timely publish or publicize the negative study results.

15. In 2003, 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 for off-label use.

16. In 2004, Abbott learned about a well-conducted, well-designed clinical trial that found Depakote to be ineffective for treatment of agitation associated with dementia, but Abbott continued to promote the off-label use of Depakote for this indication until the 2008 publication of the results of that trial. Abbott did not stop its representatives from detailing doctors about this off-label use of Depakote until at least 2006.

VIOLATIONS OF LAW

17. Paragraphs 1-16 of this complaint are incorporated herein as though set forth in full. 9 V.S.A. § 2458(a) authorizes the Attorney General to bring an action to enjoin Defendants from engaging in a method, act, or practice that is in violation of the Act. .

18. As set forth below, in the course of advertising, soliciting, selling, promoting and distributing Depakote, Abbott represented that Depakote had sponsorship, approval, characteristics, ingredients, uses, benefits, quantities or qualities that it did not have. These deceptive acts and practices are unlawful and violate the Act.

PRAYER FOR RELIEF

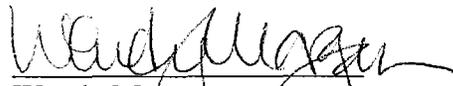
WHEREFORE, the Plaintiff prays that this honorable Court enter an Order:

- 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 any of them, from continuing to engage in unfair or deceptive conduct;
- B. Ordering Defendant to pay all costs for the prosecution and investigation of this action, as provided by 9 V.S.A. § 2458(b)(3);
- C. Ordering Defendant to pay civil penalties of \$10,000.00 pursuant to 9 V.S.A. § 2458(b)(1) for each and every violation of the Act.; and
- D. Granting such other and further relief as the Court deems equitable and proper.

Dated May 7, 2012.

Respectfully submitted,

WILLIAM H. SORRELL
ATTORNEY GENERAL
STATE OF VERMONT



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