IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT, IN AND FOR BROWARD COUNTY, FLORIDA

OFFICE OF ATTORNEY GENERAL, STATE OF FLORIDA, DEPARTMENT OF LEGAL AFFAIRS,	)	
Plaintiff,	)	**Case no.**
vs.	)	
BRISTOL-MYERS SQUIBB COMPANY	)	
Defendant.	)	

COMPLAINT

NOW COMES the Plaintiff, Office of Attorney General, State of Florida, Department of Legal Affairs and brings this action against Defendant Bristol-Myers Squibb Company for violating the Florida's Deceptive and Unfair Trade Practices Act, Chapter 501, Part II, Florida Statutes, and states as follows:

The Parties

1. Plaintiff, Office of Attorney General, State of Florida, Department of Legal Affairs (hereinafter referred to as the "Attorney General" or "Plaintiff"), is charged with, enforcing and seeking redress for violations of the State of Florida's consumer protection laws, including Florida's Deceptive and Unfair Trade Practices Act, Chapter 501, Part II, Florida Statutes ("FDUTPA").

2. Defendant Bristol-Myers Squibb Company, ("Defendant" and/or "BMS"), is a Delaware corporation with its principal place of business at 345 Park Avenue, New York, New York 10154.

3. At all relevant times hereto, Defendant BMS transacted business in the State of Florida and nationwide by advertising, soliciting, selling, promoting, marketing, and distributing prescription drugs, including the atypical antipsychotic prescription drug Abilify, and that business is governed by FDUTPA.

Jurisdiction and Venue

4. The Attorney General brings this action pursuant to FDUTPA, and is authorized to seek the relief sought herein.

5. This is an action for injunctive relief, civil penalties and other relief.

6. This Court has jurisdiction pursuant to Sections 26.012 and 501.201 et seq., Fla. Stat., as Defendant has transacted business within the State of Florida which affected multiple judicial circuits.

7. Venue is proper in this Court pursuant to Section 47.051, Fla. Stat., as Defendant BMS conducted business throughout the State of Florida including Broward County, Florida. In addition, a portion of the cause of action accrued in Broward County.

8. The State has conducted an investigation of the matters alleged herein and Attorney General Pamela Jo Bondi has determined that this enforcement action serves the public interest, as required by Section 501.207(2), Florida Statutes.

Background

9. Abilify is one of several second-generation antipsychotic prescription drugs, commonly referred to as "atypical antipsychotics," that were originally used to treat schizophrenia. Most or all of these drugs have since been approved by the Food and Drug Administration ("FDA") for a number of mental disorders.

10. These drugs can produce side effects, including cerebrovascular complications, movement disorders, diabetes, hyperglycemia and weight gain.

11. Abilify, the trade name for the drug with the generic name aripiprazole, was first approved by the FDA for the treatment of schizophrenia in November, 2002. Since then, the FDA has approved various formulations of Abilify for several indications, including the treatment of acute manic or mixed episodes in Bipolar I Disorder, the treatment of schizophrenia in adolescents, adjunctive treatment in patients with major depressive disorder, acute manic or mixed episodes associated with Bipolar I Disorder in pediatric patients, the treatment of irritability associated with autistic disorder in pediatric patients, and the treatment of Tourette's disorder.

Defendant's Course of Conduct

12. BMS began to market Abilify to health care professionals not only for the treatment of schizophrenia in 2002, but also for a number of uses for which it was not approved by the FDA. For example, BMS promoted Abilify for use in children before it was approved for children in 2007. BMS also promoted Abilify for use in patients with symptoms consistent with dementia and Alzheimer's disease despite the lack of FDA approval. In fact, ultimately Abilify received a black box warning that elderly patients with dementia-related psychosis who are treated with antipsychotic drugs have an increased risk of death.

13. In addition, BMS used "Coming Soon" posters to promote Abilify for uses for which it had not been approved by the FDA.

14. BMS implicitly misrepresented the drug's approved uses when it promoted and marketed Abilify for uses for which the drug was not approved.

15. BMS made unsubstantiated claims that Abilify was superior to other atypical antipsychotics by minimizing and misrepresenting risks of the drug, such as metabolic and weight gain side effects, thereby making false and/or misleading representations about Abilify's side effects.

Violations of the Consumer Protection Act

16. The allegations contained in paragraphs 1-15 are incorporated by reference as if they were set out at length herein.

17. The Defendant, in the course of promoting and marketing the prescription drug Abilify for off-label uses, misrepresented the drug's approved uses which had the capacity, tendency, or effect of deceiving or misleading consumers. Such misrepresentations constitute deceptive trade practices that are prohibited by FDUTPA.

18. The Defendant, in the course of promoting and marketing the prescription drug Abilify for off-label uses, represented that Abilify had approvals, characteristics, uses, benefits, and qualities that it did not have. Such misrepresentations constitute deceptive trade practices that are prohibited by FDUTPA.

19. The Defendant made representations about Abilify's side effects that had the capacity, tendency, or effect of misleading consumers. Such misrepresentations constitute deceptive trade practices that are prohibited by FDUTPA.

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 engaging in deceptive trade practices in the promotion and marketing of pharmaceutical products;

B. Ordering the Defendant to pay attorney's fees and costs for the prosecution and investigation of this action, as provided by FDUTPA;

C. Ordering the Defendant to pay civil penalties of not more than Ten Thousand Dollars ($10,000.00) for each such violation of Florida Deceptive and Unfair Trade Practices Act and civil penalties in the amount of not more than Fifteen Thousand Dollars ($15,000.00) for each such violation which victimized a person who is 60 years of age or older or handicapped persons, pursuant to Sections 501.2075 and 501.2077 Fla. Stat.;

D. Declaring Defendant's actions and practices unlawful under Chapter 501, Part II, Florida Statutes.

Respectfully submitted,

PAMELA JO BONDI
Florida Attorney General

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Dated: Dec. 8th, _____, 2016