

**IN THE COURT OF COMMON PLEAS
FRANKLIN COUNTY, OHIO**

STATE OF OHIO, <i>ex rel.</i>)	CASE NO.
MICHAEL DeWINE,)	
ATTORNEY GENERAL)	JUDGE
30 East Broad Street)	
State Office Tower – 14 th Floor)	
Columbus, Ohio 43215)	
)	
Plaintiff,)	<u>COMPLAINT FOR</u>
)	<u>DECLARATORY JUDGMENT,</u>
v.)	<u>INJUNCTIVE RELIEF, CIVIL</u>
)	<u>PENALTIES AND COSTS</u>
BRISTOL-MYERS SQUIBB)	
COMPANY)	
345 Park Avenue)	
New York, New York 10154)	
)	
Defendant.)	

1. Plaintiff, State of Ohio, by and through the Attorney General of Ohio, Michael DeWine, having reasonable cause to believe that violations of Ohio’s consumer laws have occurred, brings this action in the public interest and on behalf of the State of Ohio under the authority vested in him pursuant to R.C. 1345.07 of the Consumer Sales Practices Act.

PARTIES

2. Defendant Bristol-Myers Squibb Company (“Defendant” or “BMS”) is a Delaware corporation with its principal place of business at 345 Park Avenue, New York, New York 10154.
3. Defendant transacted business in the state of Ohio and nationwide by advertising, soliciting, selling, promoting, marketing and distributing prescription drugs, including the atypical antipsychotic prescription drug Abilify®.

4. The actions of Defendant, hereinafter described, have occurred in the State of Ohio, County of Franklin and various other counties, and as set forth below, are in violation of the Consumer Sales Practices Act, R.C. 1345.01 *et seq.*
5. Defendant is a “supplier” as that term is defined in R.C. 1345.01(C) as Defendant was, at all times relevant herein, engaged in the business of effecting “consumer transactions” by marketing, promoting, and selling prescription drugs, including Abilify®, to consumers in the State of Ohio for purposes that were primarily for personal, family or household use within the meaning specified in R.C. 1345.01(A) and (D).

JURISDICTION AND VENUE

6. Jurisdiction over the subject matter of this action lies with this Court pursuant to R.C. 1345.04 of the Consumer Sales Practices Act.
7. This Court has venue to hear this case pursuant to Ohio Civ. R. 3(B)(3), in that some of the transactions complained of herein and out of which this action arose, occurred in Franklin County.

BACKGROUND

8. 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 for a number of mental disorders.
9. Atypical antipsychotics can produce dangerous side effects, including cerebrovascular complications, movement disorders, diabetes, hyperglycemia, weight gain, and other severe conditions.

10. Abilify®, the brand name for the prescription drug aripiprazole, was first approved by the Food and Drug Administration (“FDA”) for the treatment of schizophrenia in adults in November 2002. Since then, the FDA has approved various formulations of Abilify® for several indications, including: for the acute treatment of manic and mixed episodes in Bipolar I Disorder in adults and in pediatric patients aged 10-17, for the treatment of schizophrenia in adolescent patients 13 to 17 years of age, for adjunctive treatment of major depressive disorder in adults, for the treatment of irritability associated with autistic disorder in pediatric patients aged 6 to 17 years, and for the treatment of Tourette’s disorder in pediatric patients aged 6 to 18 years.

ALLEGATIONS

11. BMS began to market Abilify® to health care professionals not only for the treatment of schizophrenia in adults in 2002, but also for a number of uses for which it was not approved by the FDA. The promotion of a drug for uses for which it is not approved by the FDA is known as off-label marketing. For example, BMS promoted Abilify® off-label for use in children. BMS also promoted Abilify® for use in elderly patients with symptoms consistent with dementia and Alzheimer’s disease without first establishing the drug’s safety and efficacy for those uses and despite the lack of FDA approval for these uses. In fact, in 2006, 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.
12. BMS implicitly misrepresented Abilify®’s approved uses when BMS promoted and marketed Abilify® for uses for which it was not approved.

13. BMS also made material omissions when, among other matters, it failed to disclose the fact that Abilify® was not approved for the uses for which it was promoted and marketed.
14. BMS made unsubstantiated claims about Abilify® 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 risks.
15. BMS overstated the findings of scientific studies, for example, by using results of a randomized controlled trial to demonstrate long term efficacy of Abilify® for stabilization and maintenance in bipolar disorder, without disclosing in BMS's marketing messages to doctors the limitations of the study.

CAUSES OF ACTION

UNFAIR OR DECEPTIVE ACTS OR PRACTICES

COUNT ONE

16. Plaintiff adopts, incorporates herein, and re-alleges paragraphs 1 through 15 as if fully set forth below.
17. 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 or tendency to deceive or mislead consumers (health care providers and patients).
18. 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.

19. Defendant, in the course of minimizing and misrepresenting risks, made false, misleading, or other representations about Abilify®'s side effects that had the capacity, tendency, or effect of deceiving or misleading consumers.
20. Defendant, in the course of overstating the findings of scientific studies in marketing messages regarding Abilify®, made false, misleading, or other representations about scientific studies that had the capacity or tendency to deceive or mislead consumers (health care providers and patients).
21. Defendant committed unfair or deceptive acts or practices in violation of the Consumer Sales Practices Act, R.C. 1345.02(B)(1) by misrepresenting that Abilify® had sponsorship, approval, performance characteristics, accessories, uses, or benefits that it did not have.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

1. Adjudge and decree that Defendant engaged in acts or practices in violation of the Consumer Sales Practices Act., R. C. 1345.01 *et seq.*, as previously set forth.
2. Permanently enjoin and restrain the Defendant from engaging in deceptive and unfair practices set forth herein and from violating the Consumer Sales Practices Act.
3. Adjudge and decree that the Defendant is liable to the State for the reasonable costs and expenses of the investigation and prosecution of the Defendant's actions.
5. Assess, fine and impose upon Defendant a civil penalty pursuant to R. C. 1345.07(D) of Twenty-Five Thousand Dollars (\$25,000.00) for each unfair or deceptive act or practice alleged herein.
6. Order that all costs in this cause be taxed against Defendant.

7. Grant Plaintiff such other and further relief as this Court deems just, equitable and appropriate.

Respectfully Submitted,

MICHAEL DeWINE
Attorney General

/s/ Michael S. Ziegler
MICHAEL S. ZIEGLER
Ohio Sup. Ct. Atty. No. 0042206
Assistant Attorney General
Consumer Protection Section
30 East Broad Street, 14th Floor
Columbus, Ohio 43215-3428
614/466-3980
866/404-4121 (facsimile)
michael.ziegler@ohioattorneygeneral.gov

Counsel for Plaintiff