

SUPREME COURT STATE OF NEW YORK
COUNTY OF NEW YORK

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PEOPLE OF THE STATE OF NEW YORK BY
ERIC T. SCHNEIDERMAN, ATTORNEY GENERAL
OF THE STATE OF NEW YORK,

PLAINTIFF,

v.

BRISTOL-MYERS SQUIBB COMPANY,

DEFENDANT.
-----X

TO: THE ABOVE NAMED DEFENDANT:

SUMMONS

Index No. _____
IAS Part _____
Justice _____

Plaintiff designates New York

County as the Place of Trial

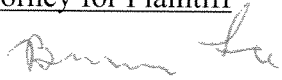
YOU ARE HEREBY SUMMONED to answer in this action and serve a copy of your answer, or if the complaint is not served with the summons to serve a notice of appearance, on the plaintiff's attorney within twenty (20) days after the service of the summons, exclusive of the day of service. If the summons is not personally served upon you, or if the summons is served upon you outside of the State of New York, then your answer or notice of appearance must be served within thirty (30) days. In case of your failure to appear or answer, judgment will be taken against you by default, for the relief demanded in the complaint.

Dated: New York, New York
December 8, 2016

Respectfully submitted,

ERIC T. SCHNEIDERMAN
Attorney General of the
State of New York
Attorney for Plaintiff

By:



Benjamin J. Lee
Assistant Attorney General
Bureau of Consumer Frauds and Protection
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SUPREME COURT STATE OF NEW YORK
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PEOPLE OF THE STATE OF NEW YORK by
ERIC T. SCHNEIDERMAN, Attorney General
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Index No.

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY.

Defendant.
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TO: THE SUPREME COURT OF THE STATE OF NEW YORK

Plaintiff, the People of the State of New York, by their attorney, Eric T. Schneiderman, Attorney General of the State of New York, alleges the following upon information and belief:

JURISDICTION & PARTIES

1. Plaintiff is the People of the State of New York, by Eric T. Schneiderman, Attorney General of the State of New York.

2. The Attorney General brings this complaint pursuant to Executive Law § 63(12) and General Business Law (“GBL”) §§ 349 and 350. Executive Law § 63(12) authorizes the Attorney General to seek injunctive relief, restitution, damages and costs when any person or business entity has engaged in or otherwise demonstrated repeated fraudulent or illegal acts in the transaction of business. GBL § 349 empowers the Attorney General to seek injunctive relief and restitution when any person or entity has engaged in deceptive acts or practices in the conduct of any business. GBL § 350 empowers the Attorney General to seek injunctive relief and restitution when any person or entity has engaged in false advertising. GBL § 350-d empowers the Attorney General to seek civil penalties in the amount of \$5,000 for each violation of GBL §§ 349 and 350.

3. 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.

4. At all relevant times hereto, Defendant BMS transacted business in the State of New York and nationwide by advertising, soliciting, selling, promoting, marketing and distributing prescription drugs, including the atypical antipsychotic prescription drug Abilify.

5. Defendant has waived its right to receive pre-litigation notice pursuant to GBL §§ 349 (c) and 350-c.

6. By marketing Abilify for uses that were not authorized by its label, by minimizing and misrepresenting the risks of the drug, and by overstating the findings of scientific studies concerning the safety and efficacy of Abilify, Defendant has engaged in repeated and persistent fraud and illegality in violation of New York Executive Law § 63 (12), deceptive acts or practices in the conduct of its business in violation of GBL § 349, and false and misleading advertising in violation of GBL § 350.

7. Accordingly, based on the above violations of New York law, the Attorney General brings this action seeking permanent injunctive relief, civil penalties, disgorgement, restitution for injured consumers and for all other proper relief.

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 treatment of 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.

Defendant’s Course of Conduct

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 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, 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 including the limited number of participants who completed the study from beginning to end as well as the limited length of time that the control group received treatment before being switched to a placebo.

FIRST CAUSE OF ACTION
VIOLATION OF GENERAL BUSINESS LAW § 350

16. Plaintiff repeats, re-alleges, and incorporates paragraphs one through fifteen contained herein.

17. GBL § 350 prohibits "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in [New York]."

18. GBL § 350-a further provides that "false advertising" is advertising that is "misleading in a material respect."

19. In the course of promoting and marketing the prescription drug Abilify for off-label uses, Defendant engaged in false advertising by the following:

- a. making material omissions concerning the drug's approved uses and those omissions deceived or tended to deceive consumers;
- b. representing that Abilify had approvals, characteristics, uses, benefits, and qualities that it did not have;
- c. making false, misleading, or other representations about Abilify's side effects that had the capacity, tendency, or effect of deceiving or misleading consumers;
- d. overstating the findings of scientific studies in marketing messages and making false, misleading, or other representations about scientific studies that had the capacity or tendency to deceive or mislead health care providers and patients.

20. By engaging in the advertising alleged above, Defendant has engaged in false advertising in violation of GBL § 350.

SECOND CAUSE OF ACTION
VIOLATION OF GENERAL BUSINESS LAW § 349

21. Plaintiff repeats, re-alleges, and incorporates paragraphs one through fifteen contained herein.

22. GBL § 349 declares unlawful “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York].”

23. In the course of promoting and marketing the prescription drug Abilify for off-label uses, Defendant engaged in deceptive acts and practices by the following:

- a. making material omissions concerning the drug's approved uses and those omissions deceived or tended to deceive consumers;

- b. representing that Abilify had approvals, characteristics, uses, benefits, and qualities that it did not have;
- c. making false, misleading, or other representations about Abilify's side effects that had the capacity, tendency, or effect of deceiving or misleading consumers;
- d. overstating the findings of scientific studies in marketing messages and making false, misleading, or other representations about scientific studies that had the capacity or tendency to deceive or mislead health care providers and patients.

24. By engaging in the acts and practices alleged above, Defendant has engaged in deceptive and misleading practices in violation of GBL § 349.

THIRD CAUSE OF ACTION
VIOLATION OF EXECUTIVE LAW § 63(12) (FRAUD)

25. Plaintiff repeats, re-alleges, and incorporates paragraphs one through fifteen contained herein.

26. Executive Law § 63(12) authorizes the Attorney General to seek injunctive relief whenever any person engages in repeated fraudulent or illegal conduct or otherwise demonstrates persistent fraud or illegality in the carrying on, conducting, or transaction of business.

27. In the course of promoting and marketing the prescription drug Abilify for off-label uses, Defendant engaged in fraudulent and illegal business practices by the following:

- a. making material omissions concerning the drug's approved uses and those omissions deceived or tended to deceive consumers;
- b. representing that Abilify had approvals, characteristics, uses, benefits, and qualities that it did not have;

- c. making false, misleading, or other representations about Abilify's side effects that had the capacity, tendency, or effect of deceiving or misleading consumers;
- d. overstating the findings of scientific studies in marketing messages and making false, misleading, or other representations about scientific studies that had the capacity or tendency to deceive or mislead health care providers and patients.

28. By the acts and practices alleged above, Defendant has engaged in repeated and persistent fraudulent and illegal conduct in violation of Executive Law § 63(12).

WHEREFORE, Plaintiff requests that this Court issue an Order and Judgment pursuant to Executive Law § 63(12) and GBL §§ 349, 350 and 350-d:

- (a) permanently enjoining Defendant from engaging in the fraudulent, deceptive and illegal conduct alleged in the Complaint;
- (b) directing Defendant to pay restitution and damages to injured consumers, known and unknown;
- (c) directing Defendant to disgorge all profits illegally obtained in order to effectuate a just result, and make payment of such amounts to the State of New York;
- (d) directing Defendant to pay a civil penalty to the State of New York pursuant to GBL § 350-d in the sum of five thousand dollars (\$5,000) for each violation of GBL § 349 and GBL § 350;
- (e) directing Defendant to pay to Plaintiff the costs of this proceeding, including the sum of two thousand dollars (\$2,000) to cover additional costs pursuant to CPLR § 8303(a)(6); and

(f) granting Plaintiff such other and further relief as the Court deems just and proper.

Dated: New York, NY
December 9, 2016

Respectfully submitted,

ERIC T. SCHNEIDERMAN
Attorney General of the State of New York
Attorney for Plaintiff

By:



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OF COUNSEL