A.G. Schneiderman Announces $19.5 Million Multi-State Agreement With Bristol-Myers Squibb To End Deceptive Advertising Practices And Off-Label Promotion Of Drug Used To Treat Schizophrenia

NEW YORK—Attorney General Eric T. Schneiderman announced today a $19.5 million multistate agreement with Bristol-Myers Squibb ("BMS") arising from alleged improper marketing and promotion of the drug Abilify. New York's share of the settlement is $788,774. Abilify is one of several second-generation antipsychotic prescription drugs, commonly referred to as "atypical antipsychotics," that were originally used to treat schizophrenia. The agreement is signed with 41 other State Attorneys General and the District of Columbia.

"Drug companies should not market their drug for off-label uses or make claims that are not supported by scientific evidence," **Attorney General Schneiderman** said. "Consumers must be able to rely on their doctor's advice for medication without having to worry about drug companies manipulating their advertising to promote their products at the expense of patients."

Abilify is the brand name for the prescription drug aripiprazole. It was originally approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia in 2002. Since then, the FDA has approved various formulations of Abilify for other indications.

In a complaint filed today in New York County Supreme Court, Attorney General Schneiderman alleges that BMS engaged in off-label marketing, which is the promotion of drugs for uses that are not FDA approved. BMS improperly promoted Abilify for pediatric use and for use in elderly patients with symptoms consistent with dementia and Alzheimer's disease. In fact, in 2006, Abilify received a "black box" warning stating that elderly patients with dementia-related psychosis who are treated with antipsychotic drugs have an increased risk of death. The complaint further that BMS violated state consumer protection laws by misrepresenting and minimizing risks of the drug including metabolic and weight gain side effects and by misrepresenting the findings of scientific studies.

The consent decree contains strong injunctive terms prohibiting BMS from:

- Promoting Abilify for off-label uses;
- Making false or misleading claims about Abilify;
- Compensating health care providers for merely attending a promotional activity for Abilify;
- Promoting Abilify by highlighting selected symptoms instead of diagnoses without reference to the FDA-approved indications;
- Using medical education grants, including Continuing Medical Education grants, or any other type of grant to promote Abilify;
- Rewarding health care providers with grants based on their prescribing habits;

- Providing samples of Abilify to health care providers whose clinical practices are inconsistent with Abilify's FDA-approved label.

States participating in the settlement include: Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.

The case was handled by Assistant Attorney General Benjamin J. Lee under the supervision of Bureau Chief Jane M. Azia in the Consumer Frauds and Protection Bureau, and Executive Deputy Attorney General of Economic Justice Manisha M. Sheth.