



PRESS RELEASE

Attorney General Frosh Leads Settlement of Consumer Protection Claim Against Bristol-Myers Squibb

Company to Pay \$19.5 Million as Part of Multi-state Settlement for Alleged Unfair and Deceptive Marketing of Drug Abilify

Baltimore, MD (December 8, 2016) – Maryland Attorney General Brian E. Frosh announced today that he, together with Kentucky Attorney General Andy Beshear, led a group of 43 Attorneys General in reaching a \$19.5 million dollar consumer protection settlement with Bristol-Myers Squibb Company (“Bristol-Myers”) related to the drug company’s alleged improper marketing of the antipsychotic drug Abilify. In a complaint filed today in court along with a consent order, Attorney General Frosh alleges that Bristol-Myers engaged in unfair or deceptive trade practices when it marketed Abilify.

“Drug marketing must be based on sound science and FDA approval, not on the whims of drug manufacturers,” said Attorney General Frosh. “Promotion of a drug for off-label, unapproved purposes often puts at risk the health of vulnerable patients, young and old alike.”

Abilify is the brand name for the prescription drug aripiprazole. The drug 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 several indications. The complaint, however, alleges that Bristol-Myers promoted Abilify for use in elderly patients with symptoms consistent with dementia and Alzheimer’s disease despite the lack of FDA approval for these uses and without first establishing the drug’s safety and efficacy for those uses. 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. Additionally, the complaint alleges that Bristol-Myers promoted Abilify for uses in children that were not approved by the FDA. Moreover, the complaint alleges that Bristol-Myers minimized and misrepresented risks, such as metabolic and weight gain side effects, thereby making false and misleading representations about Abilify’s risks. The complaint further alleges that Bristol-Myers overstated the findings of scientific studies by not revealing limitations that would materially affect

the interpretation of the study results. The active ingredient in Abilify, aripiprazole, is now available as a generic, but several product formulations are still protected by patent.

Under the terms of the settlement, Bristol-Myers' marketing of any formulation containing the active ingredient aripiprazole will be restricted. Bristol-Myers will be prohibited from making false or misleading claims about Abilify, about its safety or efficacy in comparison with other drugs, and about the implications of clinical studies relating to the drug. Bristol-Myers will also be subject to limitations on financial incentives to sales representatives and health care providers, dissemination of information that may promote the off-label use of Abilify, and other practices affecting off-label promotion.

Attorney General Frosh and Attorney General Beshear were joined by the Attorneys General of Arizona, Colorado, Delaware, District of Columbia, Florida, North Carolina, Ohio, and Pennsylvania in negotiating the settlement. The additional participating states included in the multi-state settlement are: Alabama, Arkansas, California, Connecticut, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin.