



PRESS RELEASE

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Colorado Department of Law

Attorney General Cynthia H. Coffman

Attorney General Coffman Announces \$19.5 Million Multi-State Consumer Protection Settlement with Bristol-Myers Squibb

Colorado to receive over half a million dollars in Abilify settlement

DENVER, CO – Attorney General Cynthia H. Coffman announced today that she, along with 42 other Attorneys General, reached a \$19.5 million dollar settlement with Bristol-Myers Squibb Company (“BMS”) related to the drug company’s alleged deceptive trade practices when it marketed Abilify. Colorado served on the multistate executive committee that negotiated the settlement, and will receive \$527,740.00 of the settlement funds.

The state attorneys general allege that BMS engaged in deceptive trade practices by minimizing and misrepresenting risks associated with Abilify’s use and overstating the findings of scientific studies by not revealing limitations that would materially affect the interpretation of the study results.

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 state attorneys general also allege that BMS 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 BMS promoted Abilify for uses in children not approved by the FDA.

“It is extremely important that Colorado consumers have accurate and honest information about a drug when they are evaluating treatment options, especially when they are facing serious and sometimes debilitating diseases,” said Attorney General Coffman. “My office is going to hold drug companies accountable when they mislead or deceive Coloradans.”

The settlement with BMS will restrict the company’s marketing of any formulation containing the active ingredient aripiprazole.¹ It also will prohibit BMS from making false or misleading claims about Abilify, its safety or efficacy in comparison with other drugs, and the implications of clinical studies relating to the drug. BMS will be subject to limitations on financial incentives to sales representatives and health care providers, dissemination of information that may promote off-label use of Abilify, and other practices affecting off-label promotion.

The Attorney General has filed the proposed settlement with the Denver District Court and it is awaiting court approval.

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¹ The active ingredient in Abilify, aripiprazole, is now available as a generic, but several product formulations are still protected by patent.