

Beshear Secures nearly \$335,000 for State General Fund from Settlement with Pharmaceutical Company's Antipsychotic Drug

Allegations claimed Bristol-Myers Squibb misrepresented risks to senior citizens, children

FRANKFORT, Ky. (Dec. 8, 2016) – Attorney General Andy Beshear announced today that his office will be transferring nearly \$335,000 to the state's General Fund from a multistate settlement with Bristol-Myers Squibb for unfair or deceptive trade practices with its atypical antipsychotic drug, Abilify.

Beshear and the Maryland Attorney General's Office led the investigation and negotiations of the settlement with Bristol-Myers Squibb for 43 states.

Beshear and the group of attorneys general allege that Bristol-Myers Squibb engaged in unfair or deceptive trade practices when it marketed Abilify, its brand name for the prescription drug aripiprazole, for use in elderly patients with symptoms consistent with dementia and Alzheimer's disease despite the lack of FDA approval and without first establishing the drug's safety and efficacy for those uses.

Additionally, the complaint alleges that Bristol-Myers Squibb promoted Abilify for uses in children not approved by the FDA.

"Kentuckians are entitled to know the truth about their prescription medications," Beshear said. "My office will continue to protect our citizens, especially our senior citizens and children from drug companies who put profits before patients."

Abilify was originally approved by the FDA for the treatment of schizophrenia in 2002. Since then, the FDA has approved various formulations of Abilify for several usages.

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 alleges that Bristol-Myers Squibb minimized and misrepresented risks and failed to disclose limitations of scientific studies thereby making false and misleading representations about Abilify's risks and benefits.

The company's marketing of any formulation containing the active ingredient aripiprazole will be restricted by the terms of the settlement.

Beshear said Bristol-Myers Squibb 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 Squibb will also 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, he said.