

AG files \$8-million settlement with Bayer for hiding risks of cholesterol drug

by Bend Weekly News Sources

“Bayer must register clinical trials and post study results on a national public registry”

The settlement requires the drug manufacturing giant to register its clinical trials on a national website and post the study results. Registration of clinical studies and timely posting of study results ensures that all material information from clinical trials are made available to doctors and consumers, not just studies with positive outcomes. The judgment admits no law violation.

Bayer introduced Baycol, a “statin” cholesterol-lowering drug, into the United States market in 1998. All statins carry a known risk of myopathy (a weakening of the muscles) and rhabdomyolysis (a more serious muscular disease). Through post-marketing surveillance of its product, Bayer learned that the risk for Baycol turned out to be significantly higher compared to other statins, particularly at higher doses and when combined with genfibrozil, another cholesterol-lowering drug.

The Attorneys General alleged that while Bayer informed the US Food and Drug Administration about these adverse effects, Bayer failed to adequately warn prescribers and consumers about them.

The judgment also requires Bayer to comply with all consumer protection law in the marketing, sale, and promotion of its pharmaceutical and biological products, and prohibits Bayer from making false and misleading claims relating to any such product sold in the United States.

Under the judgment, Bayer will pay the participating states a total of \$8 million, \$600,000 will be deposited into the Oregon Department of Justice Consumer Protection and Education Fund.

Consumers wanting information about this case and consumer protection in Oregon may call the Attorney General's consumer hotline at (503) 378-4320 (Salem area only), (503) 229-5576 (Portland area only), or toll-free at 1-877-877-9392. The Department of Justice is online at www.doj.state.or.us .

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