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Bayer Beats Baycol FCA Suit

By **Sindhu Sundar**

Law360, New York (July 19, 2012, 6:54 PM ET) -- A Minnesota federal judge on Thursday tossed a suit from a former employee accusing Bayer AG of misrepresenting the risks of its cholesterol drug Baycol — which was pulled after 31 deaths were linked to its use — and causing false claims to be submitted to Medicare.

U.S. District Judge Michael J. Davis dismissed with prejudice a second amended complaint by Laurie Simpson, a former Bayer senior market research analyst, finding that her False Claims Act allegations were not specific enough about which claims made to the government for Baycol were fraudulent, and which parts of those claims were false.

Judge Davis similarly dismissed her claims that if the government had known of Bayer's alleged omissions on Baycol's health risks, it would not have paid out claims under the drugmaker's contract with the U.S. Department of Defense or other federal and state insurance programs, finding she had not made any allegations linking the government's decision to pay for Baycol to the drugmaker's alleged fraud.

"Relator does not allege that Baycol did not work for all patients," Judge Davis said. "Thus, assuming that a patient was prescribed Baycol to reduce his/her cholesterol levels, and assuming Baycol successfully lowered the patient's cholesterol, there would be nothing false or fraudulent about the claim for payment for that patient."

The U.S. Department of Defense, among the federally funded agencies to contract with Bayer for the drug, had a roughly $35.6 million contract with Bayer for the drug, according to Simpson's November 2010 second amended complaint.

Baycol, also known as cerivastatin, was used to lower cholesterol in patients with heart disease, or a risk of it, with U.S. sales of the drug at roughly $290 million in 2000, the year before Bayer pulled it from the market in August 2001, when the rare muscle disorder rhabdomyolysis, or the breakdown of muscle fibers, was linked to its use, according to Simpson's complaint.

Baycol, which was approved by the FDA in 1997, is the brand name of cerivastatin, which is part of a class of drugs known as statins that physicians prescribe to lower cholesterol in hope of preventing cardiac disease.

In January 2008, Bayer agreed to pay $8 million to 30 states to settle allegations it failed to adequately warn consumers about the safety risks associated with Baycol.

Bayer did not admit any wrongdoing in the settlement, but it did agree to register any relevant clinical drug trials and studies and to post the results at the end of each study.

The cases were combined into the MDL in December 2001, and Simpson's case joined that MDL in January 2009, according to court documents.

Bayer spokeswoman Rosemarie Yancosek said in a statement Thursday that the company is pleased with the decision.

Attorneys for Simpson could not immediately be reached for comment.

Simpson is represented by Robert W. Sadowski and Raphael Katz of Diamond McCarthy LLP and Edward Normand of Boies Schiller & Flexner LLP.

Bayer is represented by Philip S. Beck and Adam Hoeflich of Bartlit Beck Herman Palenchar & Scott LLP, Susan A. Weber, James R.M. Hemmings, Ryan C. Morris and Kristin Graham Koehler of Sidley Austin LLP and Peter W. Sipkins of Dorsey & Whitney LLP.

The Simpson case is Simpson et al. v. Bayer Healthcare et al., case number 0:08-cv-05758, in the U.S. District Court for the District of Minnesota.

The MDL is In re: Baycol Products Liability Litigation, case number 0:01-md-01431, in the U.S. District Court for the District of Minnesota.

--Additional reporting by Christine Caulfield. Editing by Kat Laskowski.