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Suit: Lariam drugmaker hid side effects

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WASHINGTON, Oct. 10 (UPI) -- A San Antonio couple has filed suit in New Jersey state court charging drug giant Hoffmann-La Roche with "knowingly withholding or misrepresenting information" about side effects of its anti-malaria drug called Lariam.

The suit Wednesday by Jane L. Daehler and her husband, Dr. Robert Daehler alleges that Lariam caused "severe and debilitating mental problems, including psychosis, bizarre speech, vivid hallucinations, extreme paranoia and seizures" after Jane took it for a trip to Kenya in September 2001.

The suit says Jane Daehler had a history of depression but that Roche failed to warn U.S. doctors against giving the drug to those patients.

Attorneys said it could become the first in a wave of suits over Lariam and, if it reaches a jury, would be the first such case in which Roche is the defendant. No Lariam cases against Roche have reached a jury; they have been withdrawn, dismissed or settled, the attorneys said.

The U.S. unit of the Swiss pharmaceutical giant is based in Nutley, N.J.

"This is probably the first of a multitude of cases we will file on Lariam," said Austin, Texas, attorney Paul Smith, who has been involved in a number of high-profile suits against drug manufacturers. "Our judgment is that Lariam is a dangerous drug, and Roche has resisted proper warnings and label changes. We see this as a mounting health problem with the military and with Americans traveling throughout the world."

Roche spokesman Terry Hurley said the company has not seen the lawsuit and does not comment on pending litigation. "However, it is important to note that information about the use of Lariam and neuropsychiatric events has appeared on the product's label since it was launched in the U.S. in 1989," Hurley said.

"The package insert for Lariam, since its inception, has described adverse events reported in clinical trials and post-marketing surveillance, including neuropsychiatric events such as psychosis, convulsions, anxiety and depression following the use of Lariam," he said. "Roche takes issues of safety very seriously and is diligent in monitoring the safety of all its drugs."

The Food and Drug Administration approved Lariam for use in the U.S. in 1989 and the Centers for Disease Control and Prevention recommends it. The company says more than 5 million Americans have taken it.

The complaint alleges that after taking the second dose of Lariam, Jane Daehler believed she could talk to the dead and to animals and attempted to disrobe in public. The complaint describes Daehler having hallucinations about monkeys and delusions where she was pregnant with a monkey, in labor and breast-feeding a monkey. It says she could not bathe herself, "apparently having no idea of the purposes of ordinary soap and water," became incontinent and could not walk unassisted.

She was hospitalized in San Antonio in a lock-down mental ward where she suffered "the most dreadful hallucinations imaginable," including that dead people were stabbing persons around her, and she could not recognize her own name or her husband, who is a medical doctor, according to the complaint.

The complaint says that while Jane Daehler had suffered depression in the past and was taking anti-depressants, Lariam's label at the time warned only that patients should not take Lariam if they suffer from active clinical depression or have a history of psychosis or convulsions. At the same time in Europe, Roche was warning that patients with a history of depression should not take the drug, the suit says.

In July 2002, Roche updated Lariam's U.S. label to warn that patients "with a recent history of depression" should not take Lariam. The new label also warns of rare reports of suicide and mental problems that have been reported to last

"long after" taking the drug.

A warning in bold on the latest label says that Lariam "may cause psychiatric symptoms in a number of patients, ranging from anxiety, paranoia, and depression to hallucinations and psychotic behavior."

In May, Roche and the widow of an Ohio man settled a suit alleging that Lariam triggered the suicide of her husband.

The Daehler case was filed in state court, where plaintiffs in product liability cases are generally believed to have better odds than in federal court.

Lariam also made news this summer, after three Fort Bragg soldiers given the drug during deployment in Afghanistan returned home and allegedly killed their wives. Two also committed suicide.

Roche spokesman Hurley said that all drugs have side effects but that the risk-benefit ratio for Lariam remains positive.

"Lariam has been used effectively for treating and preventing malaria by more than 25 million people worldwide over the past 17 years," he said. "There are more than 300 million new cases of malaria per year, resulting in an estimated two million deaths per year."

"Studies show that without the benefit of malaria prophylaxis, travelers to malarious areas with high rates of transmission of malaria have about a 1 in 100 chance of contracting the disease."

Attorneys working on the Daehler case also represent the majority of more than two dozen plaintiffs alleging that Roche's anti-acne drug, Accutane, causes suicide, including the mother of Charles Bishop. She claims Accutane made Bishop, 15, fly a Cessna plane into a Tampa high-rise in January.

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