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## Drug firm warns of Lariam suicide reports

By Mark Benjamin and Dan Olmsted

From the [Washington Politics & Policy Desk](#)

Published 8/26/2002 6:57 PM

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WASHINGTON, Aug. 26 (UPI) -- The manufacturer of the controversial anti-malaria drug Lariam has begun warning in the drug's official product information about reports of suicide.

The company also now says patients should be told that mental problems such as acute anxiety or depression could signal the start of "a more serious event," and they should switch medications if they experience them.

On May 21, United Press International reported mounting evidence suggesting Lariam has caused mental problems so severe that in a small percentage of cases it has triggered suicide.

At that point, Lariam's official product information only mentioned "suicidal ideation" -- thinking about suicide -- in the section headed "Less frequently reported adverse events." Mental problems linked to the drug, and a reference to reports of suicide, now also appear in the section titled "Warnings."

The updated information was posted, without publicity, on drug-maker Hoffmann-La Roche's Web site last month and caught a Food and Drug Administration spokesman by surprise Monday when UPI asked about it.

A drug's product information -- known as the label -- is provided for doctors and pharmacists. Patients often do not receive it.

Susan Rose, an adjunct assistant professor at George Washington University's public health school, and an advocate for people who claim Lariam has caused severe mental problems leading to suicides, aggressive behavior and psychosis, said Monday the information could save lives and should be widely publicized by the drug company.

"We are planning a mailing to health care professionals outlining changes to the revised Lariam package insert," said a statement from the company, which added that the changes were the result "of our continued collaboration with the FDA to manage the safety of Lariam in order for travelers to use the product responsibly and safely."

Earlier this month, UPI reported that three Fort Bragg, N.C., soldiers suspected of killing their wives had been given Lariam while deployed in Afghanistan. Two of those soldiers committed suicide after shooting their wives, authorities said.

Possible psychiatric side effects of the drug are among a wide range of factors being examined by an Army epidemiology team that arrived Sunday at the North Carolina base.

On Monday, the London Daily Telegraph reported that a Cambridge University student who suffered from depression after taking Lariam committed suicide Friday.

Vanessa Brunt, 22, took Lariam in 1999 during a year away from school.

"We are in no doubt that the tablets caused the illness -- Vanessa became physically and mentally ill within weeks of taking them," her father, Michael, told the paper.

The company says that Lariam is effective against malaria, and that while no medicine is completely without side effects, Lariam is "not associated with violent, criminal conduct."

The drug's new FDA-approved label states in bold type: "Rare cases of suicidal ideation and suicide have been reported though no relationship to drug administration has been confirmed."

The same section also states: "Mefloquine (the generic name for Lariam) may cause psychiatric symptoms in a number of patients, ranging from anxiety, paranoia, and depression to hallucinations and psychotic behavior. On

occasion, these symptoms have been reported to continue long after mefloquine has been stopped."

FDA spokesman Jason Brodsky noted that information on severe side effects had been added to the "Warnings" section on the label to increase awareness among health professionals and travelers.

He also pointed out that a section titled "Information for patients" had been strengthened. It now says patients should be advised that if they "experience psychiatric symptoms such as acute anxiety, depression, restlessness or confusion, these may be considered prodromal (preliminary) to a more serious event. In these cases, the drug must be discontinued and an alternative medication should be substituted."

The previous label said only that patients should be advised that some people can't take Lariam because of "side effects" and that "if the patient experiences any symptoms that may affect the patient's ability to take this drug," they should contact their doctor and might need to change medication.

Brodsky said "there's no confirmed attribution" to reports of suicide and that the FDA believes that concern over side effects should not outweigh awareness of Lariam's effectiveness in preventing malaria.

"The risk of death from malaria as a result of not using prophylaxis (prevention) far outweighs the remote possible risk of suicide associated with Lariam," he said.

Lariam is one of three drugs recommended by the Centers for Disease Control and Prevention for the prevention of malaria. The other two must be taken daily; Lariam is taken weekly. The FDA says that is a strong argument in favor of Lariam, because if travelers forget even one dose of the daily pills, they are at risk of catching malaria.

UPI has been conducting a six-month investigation of Lariam.

-- In the May 21 article, UPI reported that in thousands of pages of internal documents spanning a decade, Hoffmann-La Roche tracked increasing reports of suicides, suicidal behavior and other mental problems among Lariam users. A review of four years of reports filed to the FDA found 11 suicides attributed to Lariam, and one expert on drug side effects said he believes the number easily could be 100 times higher.

-- In July, UPI reported that scores of Peace Corps volunteers are coming forward saying that during the past 12 years, they suffered crippling paranoia, anxiety, hallucinations, memory loss, suicidal behavior and physical ailments they attributed to Lariam. Many volunteers said the problems had persisted for years. Sen. Chris Dodd, D-Conn., who chairs the committee overseeing the Peace Corps and is a former volunteer, called for an independent medical investigation of the matter based on the UPI report.

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