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Suicides, attempts from FDA database

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WASHINGTON, May 21 (UPI) -- Reports of 11 suicides and 12 suicide attempts associated with the anti-malaria drug Lariam were filed with the Food and Drug Administration between October 1997 and September 2001, according to the agency and a United Press International search of the FDA's MedWatch adverse events database.

Most of those reports were obtained by UPI, under a Freedom of Information Act request, and they are summarized below.

Health professionals are frequently the source of MedWatch reports, but anyone who believes a drug might have caused a side effect can send in the one-page document from anywhere in the world.

This system is completely voluntary, and the FDA says it receives reports on 1 percent to 10 percent of total side effects.

Drug manufacturers -- in Lariam's case Hoffmann-La Roche, the Swiss pharmaceutical giant with U.S. headquarters in Nutley, N.J. -- are required to submit within 15 days all reports they receive of possible side effects that are serious and unexpected.

The FDA states on the MedWatch form that "Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event."

The reports are in the order in which they arrived in the FDA packet. Names and identifying information were blacked out by the FDA.

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Suicide attempt. Submitted Jan. 13, 2000. A 23-year-old woman was hospitalized for acute psychosis. "The patient had no history of previous psychiatric illness. The patient is a Canadian exchange student in Hong Kong and was going to Cambodia for a three-week vacation...About four hours after her last dose, the patient became totally psychotic. The patient then stole two infant babies in push carts and was taken to the police station. The patient then attempted suicide and jumped off a roof. The patient was taken to a clinic and treated for psychosis. A physician from [deleted] was flown in and escorted her back to [deleted]. The patient was hospitalized ... The patient was still psychotic and experiencing hallucinations. She attempted suicide again by jumping from the seventh floor."

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Suicide. Submitted June 30, 1998. "A 40-year-old male patient committed suicide by hanging himself after using Lariam...He was admitted to a psychiatric ward and was diagnosed with having a fragile personality due to a disturbed childhood, failed marriage and atrocities he witnessed in Africa. He attempted suicide 3 times...The patient committed suicide by hanging himself. The coroner found that the patient had committed suicide whilst the balance of his mind was disturbed. The reporter considered the event possibly related to the suspect drug (Lariam) or the patient's fragile personality/disturbed childhood/failed marriage."

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Suicide. Submitted Oct. 13, 1998. Report of "a 29-year-old male patient who experienced medically significant depression and mania and died from committing suicide following the use of Lariam...The patient had no psychiatric history...Apr. 96: Lariam therapy started...Apr. 97: The patient developed hypomania (a mild form of mania). Unknown date: She experienced a prolonged depressive episode. Spring 98: The patient died from committing suicide. The depression had not resolved and the outcome of the mania had not been specified."

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Suicide. Submitted May 21, 2001. Although his name is blacked out, this is a report of the suicide of Charles Perry of Bethel, Ohio, who killed himself with a shotgun in January 1999. "A 53-year-old male patient developed obsessive compulsive disorder, delusional disorder (paranoid type), auditory and visual hallucinations, depression, CNS

(central nervous system) problems...cognitive impairment...delirium, memory loss, agitation, sweating, adjustment disorder, anxiety, insomnia, fatigue...head pain, abnormal dreams and anorexia during the use of Lariam...and committed suicide...The patient did not have a history of psychiatric disorders." Perry's widow, Linda Perry, sued manufacturer Hoffmann-La Roche for allegedly failing to warn about the drug's side effects including suicide; Roche denied the charge. The case recently was settled out of court. The terms were not disclosed.

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Suicide. Submitted Feb. 21, 2000. This report was taken from an article in a medical journal; the man was given a treatment dose of Lariam (much higher than the preventive dose) for suspected malaria. "A 33-year-old male patient experienced psychosis, depression, confusion and anxiety and subsequently committed suicide during the use of Lariam for suspected malaria....In 1995 he took Lariam for malaria (prevention)...for half a year in central Africa (with no associated adverse events)...2 Jan 2000: The patient took a single dose of 500 MG Lariam...Four hours later, he experienced an increasing headache, bone pain...slight numbness of the face and dizziness. Twelve hours later he became confused. He was disorientated and afraid of the dark...5 Jan 2000...The patient's psychosis continued. After writing a suicide note, the patient committed suicide by cutting his throat with a penknife."

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Suicide. Submitted Aug. 21, 2000. "This spontaneous case was forwarded by a lawyer who retrieved the information from an Internet site which described a male patient of unknown age who committed suicide...The patient went on safari. After his travels he was observed to have become a different person and not long after he returned he committed suicide. There was no further information."

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Suicide. Submitted Sept. 18, 2000. "This report...concerns a 36-year-old male patient, who committed suicide during/following the use of Lariam...The patient had no previous history of depression...The patient committed suicide while on a business trip to West Africa. No further information was available."

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Suicide. Submitted Dec. 8, 1997. "A male patient, age unspecified, committed suicide during the use of Lariam and following the use of chloroquine, both for malarial (prevention)...Jan 97 (approx): Chloroquine therapy was commenced as the patient was traveling to Nicaragua. Apr. 97 (approx): The patient experienced unspecified reactions. His wife noted that he acted differently towards her and his general behaviour had changed. The patient consulted his family doctor who then prescribed Lariam therapy as a replacement. May 97 (approx): The patient committed suicide."

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Suicide. Submitted Feb. 16, 1998. "A 33-year-old male patient committed suicide (by hanging) following the use of Lariam...There was no personal or family history of depression or psychological disorder...06 Oct. 96: Lariam was started...13 Oct.-21 Nov. 96: The patient took his 8th and last dose of Lariam...22 Dec. 96: The patient hanged himself and subsequently died. Police investigation ruled out external influence. The patient had shown no psychological signs."

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Suicide attempt. Submitted Sept. 4, 1998. "A 30-year-old female patient attempted suicide following the use of Lariam for malaria. She also (complained of) depression, restlessness and insomnia...There is a relevant history of psychosis (brother)."

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Suicide attempt. Submitted Aug. 9, 2000. An 18-year-old man took Lariam and another drug listed as an "unknown paracetamol product"; both were listed under "suspect medications." "Consumer felt that people were talking about him...Consumer became withdrawn and believed himself to be stupid. In May of 2000, consumer took an overdose...Patient reportedly recovered from suicide attempt following treatment but has not recovered from apathy and paranoia."

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Suicide attempt. Submitted Feb. 3, 2000. "A 59-year-old female patient made suicide attempts and experienced paranoia following the use of Lariam...The patient (developed) a psychiatric disorder. This consisted of paranoia with evidence of suicidal acts." The person making the report, a health professional, "considered that the psychiatric disorder had been life-threatening and was probably related to the use of Lariam."

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Suicide attempt. Submitted Oct. 19, 2000. Report by a physician about a 47-year-old man with a history of depression. "After he received the seventh tablet, the patient attempted suicide requiring hospitalization."

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Suicide attempt. Submitted Jan. 23, 2001. Report from French medical authorities about a 35-year-old man who "attempted suicide, developed life-threatening psychosis and experienced paranoid reaction...headache and dizziness during the use of Lariam...for a trip to Cameroon. The patient has no medical history and took no concomitant medication." The person who reported the attempt "listed the drug relationship for suicide attempt and psychosis as remotely related to Lariam."

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Suicide attempt. Submitted Oct. 5, 2000. A 42-year-old woman "was hospitalized due to a suicide attempt after having received Lariam" for malaria prevention. She had "delirium, anxiety and behaviour disturbances (signs of persecution and an urge to run away.)"

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Suicide attempt. Submitted Nov. 10, 2000. A 20-year-old college student with a history of depression and obsessional thoughts "developed depression, agitation and suicidal thoughts." 5 March 91: Depression, nervousness, trembling, agitation, shaking hands. Seen by physician in [deleted] and told the symptoms were due to Lariam...12 April 91: Patient attempted suicide with an overdose of Tylenol. Hospitalization for 2 days."

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