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Jay S Cohen, MD interviewed Sue Rose, MPH, JD and Jeanne Lese, MA, Co-Directors of [Lariam Action USA](#) for MedicationSense newsletter. The original interview from May 2007 is posted at www.medicationsense.com.

Lariam (mefloquine) is a widely prescribed anti-malarial drug that for years was the CDC's "drug of choice" for malaria prevention. But since it came on the market (1989), there have been nagging questions about the drug's safety—questions the medical community has largely ignored. [Disclosure: neither Rose nor Lese has ever taken Lariam.]

1. Why was Lariam (mefloquine) developed?

During the Vietnam war, malaria was a huge problem for U.S. ground troops as the parasite had developed resistance to the standard anti-malarial drug, chloroquine. Mefloquine was the result of Walter Reed Army Institute of Research (WRAIR)'s program to discover a new compound to protect the troops from chloroquine-resistant malaria. Walter Reed later gave Hoffmann-La Roche the license to market Lariam to the public.

2. What are Lariam's side effects?

Adverse heart, kidney, liver, skin, central and peripheral nervous system and psychiatric effects are listed on the label as side effects from Lariam use.

Neuropsychiatric side effects such as damage to the central nervous system, dizziness, depression, acute anxiety, mania, aggression, rage, psychosis, confusion and memory loss are common.

Physical effects—seizures, insomnia, visual disturbances, ringing in the ears, impaired balance, and severe skin lesions—are well documented. Alarming, mefloquine can also cause suicides, suicidal ideation, and brain damage. These adverse effects present an unacceptable risk in a drug primarily given to healthy people.

3. I've heard that "serious" side effects from Lariam occur only in 1 in 10,000 cases. Where did this number come from?

Before we talk about numbers, let's look at the term "serious." Roche uses the drug industry's standard and very limited definition — "serious" effects are fatal, life threatening, lead to or prolong a hospital stay, or result in severe disability. This definition is inappropriate to describe Lariam's side effects. People with mefloquine toxicity typically do not die, become disabled, or land in the hospital. A 1996 British study provides a term that better fits the mefloquine profile. The study says an adverse effect is "significant [if it] prevents the traveler from undertaking the activity for which he or she had made the journey."

As for numbers, Roche is less than candid when it says serious effects from Lariam only occur in "1 in 10,000" cases. Note however that this figure is an estimate, not the result of research. It first appeared in a 1991 report from the World Health Organization's Malaria Control Unit and Hoffmann-La Roche's Drug Safety Unit. This committee arrived at the estimate by assuming a 50% adverse reaction reporting rate – a rate with no bearing on reality. A more realistic approach comes from the FDA, which states that adverse reactions are reported only between 1 and 10% of the time. When one considers the 1991 WHO committee estimate in light of the FDA statement, the incidence of significant or "serious" side effects from mefloquine readjusts to a much more realistic estimate: 1 in 2000.

4. What has research found about the true frequency of Lariam toxicity?

In 1996 the UK's MASTA study stated that 1 in 140 travelers taking mefloquine would experience adverse neuropsychiatric effects serious enough to interfere with daily activities.

In 2001 a report of randomized, blinded clinical trials conducted at 15 travel clinics in The Netherlands, Germany, the United Kingdom, Canada, and South Africa was published. Lariam was compared to another anti-malarial drug (Malarone). The results: Lariam-treated patients showed a **29%** frequency of neuro-psychiatric adverse events; **19%** of these events were rated moderate to severe.

In 2003, the *British Medical Journal* published research by Swiss scientists comparing Lariam to three other anti-malarial drugs. They found that **41.6%** of the patients taking Lariam experienced moderate to severe neuropsychiatric side effects, almost twice as many as those taking Malarone or other antimalarial drugs.

5. Is there any evidence that mefloquine damage can be permanent?

Yes. Lariam causes neurotoxicity, as reported by Dow et al. at Walter Reed Army Institute of Research in 2004 and 2006. Their studies of laboratory animals

conclude that this damage is permanent—a fact that should alarm clinicians. Since the early 1990s human patients taking mefloquine have been diagnosed with long-term brain damage, specifically to their central vestibular system, in the brain. This raises the question of **why animal research such as Dow's was not done prior to licensing** the drug.

“[H]ad this understanding of mefloquine been available prior to licensing, as it should have been, it is certain that the FDA and other national licensing authorities . . . would not have endorsed this drug,” says Dr. Ashley Croft, a world expert on Lariam in *“A Lesson Learnt: the rise and fall of Lariam and Halfan.” Journal of the Royal Society of Medicine*, April 2007.

6. Lariam prescriptions must be accompanied by a “Consumer Medication Guide.” That’s unusual, isn’t it?

It is. Significantly, Roche has updated its warnings for Lariam four times in recent years, each time strengthening the warnings. In 2002, the word “suicide” was added to Lariam’s label. The U.S. was the first country to require this addition to the label.

Lariam was a factor in three of the four murders and suicides at Ft. Bragg involving soldiers returned from Afghanistan. Although the Army’s “report” was self-serving, the public response to media attention about the Ft Bragg tragedies undoubtedly impacted the FDA.

In July 2003 the FDA initiated a new requirement: patients were to receive a plain-English consumer guide with easy to understand warnings, along with their tablets. Such patient medication guides are required of only 18 of the thousands of drugs approved by FDA.

The consumer guide says Lariam has been associated with “serious psychiatric adverse events” that “may persist even after stopping the medication.” It states “rare reports have claimed that Lariam users think about killing themselves” and notes “rarer reports of suicides.”

One major omission is the total lack of information about the scientifically established frequency of neuro-psychiatric side effects caused by mefloquine—details any reasonable person would want to know before deciding what to take for anti-malarial protection.

7. What are the main goals of Lariam Action USA?

a. To provide information about mefloquine and support to people suffering from mefloquine’s adverse effects.

b. To create awareness in the medical community and among the public that mefloquine use can result in significant physical and mental adverse effects that can be long-lasting, even permanent.

c. To promote the re-evaluation of the use of mefloquine by Congress, the Pentagon, and the FDA. The

drug should be reserved to treat malaria, not used to prevent it. It is unreasonable to continue to market a drug with a well-known toxic history when other equally effective drugs are available.

d. To inform the public that there are effective and safer alternatives to mefloquine.

e. To inform the public that Lariam (mefloquine) is a “chemical cousin” to the fluoroquinolone antibiotics (such as Cipro, Levaquin, Tequin, Avelox, Floxin,* Noroxin, and their generics). The FQ antibiotics cause adverse reactions strikingly similar to those of Lariam. People who have adverse reactions to Lariam should think twice before taking a fluoroquinolone, and vice versa.

***Withdrawn from market.**

8. How has Lariam Action USA advocated against mefloquine? What methods have you used?

Lariam Action USA, an unfunded advocacy organization, is run by two volunteer co-directors who do the work and pay the bills! We use email, a listserv, newsalerts, and a website, and we’ll soon have a blog: <http://liariamsurvivors.blogspot.com>.

TV, radio, print and internet journalists have covered the mefloquine story. Even “Law and Order” had an episode about a malaria drug with alarming side effects (see www.liarainfo.org for details). Unfortunately, despite all this publicity, not much has changed.

“*Taken As Directed*,” a documentary film, is our latest effort to broadcast the truth about mefloquine’s toxic effects on healthy people. The film shows what Lariam has done to five people who were completely healthy until they took the first dose. DVDs are available at www.takenasdirected.com.

9. I’m surprised that after all this, “Lariam” isn’t a household word (like Cipro!). What can readers do to spread the word about these problems?

Patients and physicians must wake up to the adverse effects of everyday prescriptions drugs. Mefloquine is one of countless drugs with dangerous side effects.

In Sept 2007 the *Archives of Internal Medicine* reported that FDA MedWatch reports increased by 157% between 1998--2005. Deaths from adverse drug events jumped from 5,500 to 15,107 during the same period — a cause for alarm.

You can help us work for changes in the way mefloquine is prescribed by telling people about the work of [Lariam Action USA](http://www.liarimactionusa.org) and buying a DVD of “Taken As Directed.” On a personal level, learn about the effects of the prescription drugs you take. Advocate for yourself and your family.