



Senator Feinstein Urges HHS To Evaluate Safety of  
Larium Use by Americans Overseas  
May 24, 2004

**Washington, DC** –U.S. Senator Dianne Feinstein (*D-Calif.*) today called on the Health & Human Services Department (HHS) to study the safety of Larium use as an antimalarial drug by Americans and sought more thorough reporting by HHS and the Food & Drug Administration about the side effects stemming from the drug’s use by Americans overseas. Six soldiers who recently used Larium while serving in the Middle East have experienced permanent brainstem and vestibular damage, conditions which cause hearing difficulties and problems with maintaining balance.

In a letter sent to Health & Human Services Secretary Tommy Thompson Monday, Senator Feinstein wrote:

“I am writing to express my concerns about the Defense Department’s use of the drug Larium (mefloquine) as an antimalarial for its service members deployed to Iraq and Kuwait. You may be aware that six service members have been diagnosed with permanent brainstem and vestibular damage from being given this drug despite that fact that alternative drugs might have been chosen to prevent infection.

In testimony before the House Armed Services Committee, Lt. Gen. James Peake, Surgeon General, U.S. Army, Commander, U.S. Medical Command indicated that the Department of Defense was moving to chloroquine in Iraq because it had determined that the region was not chloroquine-resistant. However, since at least as early as May 2003, the Centers for Disease Control’s website said, ‘Chloroquine is the recommended antimalarial drug for Iraq, Syria, and Turkey.’

After asking the Department of Defense and the Peace Corps, which both dispense mefloquine to their personnel, about their procedures for adverse event reporting, it appears that there may be huge gaps in the reporting of side effects of this drug. I have concerns that, since most of the people taking the product are consuming it overseas, the Department of Health and Human Services and the American public really do not have a clear understanding of the serious risks associated with taking this drug.

My additional concerns include:

- the concurrent use of ciprofloxacin, another member of the quinolone class of drugs, which soldiers are told to take whenever they consume “suspicious foods” potentially increasing risks of serious side effects;
- the side effects of mefloquine which can permanently impair affected individuals with vestibular and brain stem damage;

- the highly stressful deployment conditions create high levels of anxiety that may make service members more susceptible to serious adverse events. Many responses to deployment are very similar to conditions listed in the contraindications section of mefloquine product labelling.

I ask that you assist with an evaluation of the safety of mefloquine and help ensure that side effects are reported to the Food & Drug Administration (FDA). Specifically, I ask that you:

- work with FDA to reassess the safety of mefloquine, including working with the Department of Defense to evaluate the safety of this drug under highly stressful conditions, including deployment situations;
- work with the Department of Defense, State Department, U.S. Agency for International Development and the Peace Corps, ensuring that mefloquine medication guides are distributed to individuals given the product; and,
- work toward establishing programs to ensure the reporting of adverse events to the FDA for all products, but particularly mefloquine, by service members, other employees of the Department of Defense, State Department, U.S. Agency for International Development and Peace Corps Volunteers or their health care providers while overseas.

Thank you for your attention to this important matter. For your reference, I have attached the letter I wrote to Lester Crawford, Acting Commissioner of the Food and Drug Administration on April 1, 2004 stating my concerns about adverse events associated with mefloquine. To date, I have not received a response to my April 1 letter. I look forward to hearing from you in the near future.”

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