



Senator Feinstein Urges CDC
To Review Its Recommendations on Anti-Malarial Drug
June 14, 2004

Washington, DC – Concerned about the use of Lariam by American soldiers and civilians in Iraq and Afghanistan, Senator Dianne Feinstein (D-Calif.) has urged the Centers for Disease Control (CDC) to review its recommendation of the anti-malarial drug.

Senator Feinstein also asked the CDC to make international travelers aware of the need to report to their health care provider or the Food and Drug Administration any side effects suffered after taking the drug.

Lariam, also known by the generic name mefloquine, has recently been found to have caused vestibular and cerebral damage in ten U.S. service members and may be linked to suicides and other violent behavior by its users.

Following is the text of the letter sent Thursday to Dr. Julie Gerberding, Director of the Centers for Disease Control:

“I am writing to express my concerns about the anti-malarial drug mefloquine and to ask that you look into this drug as the CDC’s recommended drug for chemoprophylaxis in areas where chloroquine-resistant malaria is known to exist. The CDC serves as the expert reference for recommendations on chemoprophylaxis for travelers visiting foreign countries and government entities sending personnel abroad. Recently there has been much attention paid to the side effects associated with mefloquine which is recommended by the CDC and used by the Department of Defense (DoD) for service members in Iraq and Afghanistan.

Mefloquine’s labeling notes serious side effects, because of which, it is not given to pilots and certain other military personnel. As of last week, ten service members have been diagnosed with permanent vestibular and cerebral damage associated with mefloquine use. Additionally, concerns link mefloquine to suicides and other violent behavior in Special Forces and other military personnel currently under investigation within DoD.

U.S. entities sending substantial numbers of U.S. citizens overseas include, but are not limited to, DoD, the U.S. Agency for International Development, the Peace Corps and the State Department, making the Federal government a major purchaser of anti-malarial drugs in the United States. Although reporting of adverse events is voluntary, I am concerned about whether these entities have established an adequate system for reporting adverse events experienced by their personnel overseas and whether those adverse events are being reported to the drug manufacturer or the FDA to ensure that an accurate and timely safety profile is generated.

I would like to know more about the CDC's decision to make mefloquine the "drug of choice" for chloroquine-resistant regions. In light of the recent diagnosis of ten service members with permanent vestibular and cerebral damage, in addition to the July 2003 labeling changes which provided new information about serious long term effects of mefloquine, can you tell me what information the CDC needs before it can update its recommendations?

Additional questions and concerns I have include:

- **How does CDC evaluate a drug it may recommend as a drug of choice for malaria chemoprophylaxis? What would prompt a review of this choice?**
- **What information is made available in recommendations to travelers or agencies establishing formularies for anti-malarial chemoprophylaxis? Does this information include medication guides, up to date lists of contraindications and possible side effects? Since the CDC is a primary source of information about preventing malaria, does it also inform travelers and federal agencies about the need to report side effects from medications used to prevent malaria so that an accurate safety profile may be maintained?**
- **How does CDC interact with other federal entities choosing drugs for anti-malarial chemoprophylaxis to be used by personnel?**
- **How often is information provided about antimalarial drugs reviewed and updated? Is outdated information removed from websites or labeled "outdated"?**
- **What can CDC do to help ensure more comprehensive reporting of adverse events by U.S. citizens, including agents of the Federal government, while they are abroad?**

I thank you for your prompt attention to this matter and I look forward to hearing from you."

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