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Feinstein to Rumsfeld: Review malaria drug

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WASHINGTON, Nov. 4 (UPI) -- Sen. Dianne Feinstein wants the U.S. military to reassess its use of the anti-malaria drug Lariam, prescribed to some troops in Iraq, because of what she calls "growing evidence about Lariam's dangerous side effects" and complaints by troops that it has damaged their health.

"Given the mounting concerns about Lariam as expressed by civilians, service members and medical experts about its known serious side effects, I strongly urge you to reassess the (Department of Defense) policy on the use of Lariam," the California Democrat wrote Defense Secretary Donald Rumsfeld in a letter dated Oct. 29.

In the short term, Feinstein said, the military should "immediately provide service members with information about Lariam's potential side effects," more closely monitor troops for problems and offer easy access to alternatives.

The Pentagon declined to comment on the letter. In the past, military medical officials have said that the drug has proven its worth and hasn't caused serious problems. "Our point of view is Lariam is a very useful medication in preventing a dangerous disease, and our experiences with it have been good," Virginia Stephanakis, a spokeswoman for the Army surgeon general's office, told United Press International earlier this year.

Lariam was developed by the U.S. Army in the 1970s, licensed to Swiss drug giant Hoffmann-La Roche and approved for use in the United States in 1989. The drug label warns of mental and neurological problems in a number of people who take it, including aggression, suicidal thinking, psychosis and depression. In some cases, those effects have been reported to last long after a person stops taking it.

Last year, Roche changed the product label to warn of "rare cases" of suicide, and the Food and Drug Administration has ordered the company to provide detailed written warnings to each person to whom it is prescribed.

Last month, the Pentagon said that nearly 4,000 U.S. troops have been medically evacuated from Operation Iraqi Freedom for non-combat reasons -- with more than one in five of those for psychiatric or neurological problems, according to Pentagon data.

"Clearly there is more detail that needs to be given about the nature and causes of these evacuations," said Steve Robinson, executive director of the National Gulf War Resource Center. "Under psychiatric problems, how many of these could be related to Lariam?"

In her letter, Feinstein raised the possibility that fear of the drug might have led to an outbreak of malaria in more than 100 U.S. troops deployed to Liberia in August.

"While news reports of preliminary interviews with sick soldiers suggest that complacency was the primary factor behind their decision not to take their Lariam pill, I am concerned that first hand experience with its side effects and reports from fellow service members may have played some role in their decision not to take Lariam," Feinstein wrote.

The letter cited the experience of Navy Cmdr. William Manofsky, who volunteered to go to Kuwait as part of Operation Iraqi Freedom last December and began taking Lariam. By the time he returned to California in March, the letter said, "he experienced insomnia, aggression, agitation, rage, mood swings, acute nausea, vomiting, severe anxiety, depression, cognitive disorders and at times difficulty walking and communicating, conditions which placed him in the emergency room five times.

"Unfortunately, doctors have informed Cmdr. Manofsky that some of these conditions may be permanent."

Manofsky was the subject of a Sept. 8 article by United Press International, in which he alleged that the

Navy had altered his medical records to remove mention of Lariam. Manofsky provided before-and-after pages from his medical chart that appeared to show that references to the drug were missing. The Navy surgeon general's office said at the time that it was working to resolve the matter. Spokesman Brian Badura did not return a call Monday seeking comment.

Susan Rose, co-director of Lariam Action USA, a group made up of people who believe they have been harmed by the drug, welcomed Feinstein's letter and said: "Contrary to the FDA's assertion that most people can tolerate the drug, scientific studies prove that 1 in 3 will suffer a neuropsychiatric adverse event and 1 in 5 will describe it as moderate to severe."

An Army spokesman told UPI the rate of serious side effects is 1 in 13,000.

Feinstein's letter marks the second time a member of Congress has written Rumsfeld about the drug. In May 2002, Rep. John McHugh, R-N.Y., wrote asking for a review of the military's use of Lariam out of concern that it might cause mental problems among troops.

Assistant Secretary of Defense William Winkenwerder Jr. responded to McHugh that reactions to the drug had been few and generally mild among service members. But he added, "Sufficient evidence exists to raise the question whether the neuropsychiatric adverse events of mefloquine (the generic name for Lariam) are frequent enough and severe enough to warrant limiting its use. However, sufficient evidence does not exist to answer the question, especially in the case of military personnel."

UPI reporters began an investigation of Lariam in early 2002 and found that mounting evidence suggests it has triggered side effects so severe that in a small percentage of users it has led to suicide. UPI also reported that soldiers involved in a string of murder-suicides at Fort Bragg in the summer of 2002 after returning from Afghanistan had taken the drug, and that they exhibited some behavior that matched known side effects.

The Army surgeon general's office dispatched a team to investigate. It reported last November that the drug did not cause the entire cluster of deaths because not everyone suspected in the homicides had taken it, but didn't investigate whether the drug had caused any individual murder-suicide. The report said the only common thread was marital problems, perhaps aggravated by the stress of frequent deployments.

Roche, the manufacturer, says there is no reliable scientific evidence that Lariam can cause violent behavior.

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