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INSIGHT

Harmful Side Effects of Lariam

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JONATHAN MANN, CNN HOST: What's in the little white pill? Thousands of U.S. soldiers in Iraq were given a drug they didn't know much about. Now there are questions about side effects and suicide. Hello and welcome.

As the investigation into prison abuse in Iraq intensifies, the U.S. government is finding out things it didn't know about the war there in the news that's making headlines. A bit further from the front page a different kind of story is emerging, about a drug given to thousands of U.S. military personnel, a drug with sometimes dangerous side effects.

On our program today, a second look at Lariam.

(BEGIN VIDEOTAPE)

MANN (voice-over): Bill Manofsky and his wife, Tori, are looking for a new home. They aren't moving because of a new job but because Bill can't do his old one. Manofsky, a commander in the U.S. Naval Reserves, is relocating near San Diego for medical care.

BILL MANOFSKY, FMR. U.S. NAVY COMMANDER: My ears ring. They're ringing now. Mostly my right ear. I have aphasia, where I have trouble talking sometimes, where I forget what I'm trying to talk about. Short-term memory is really bad. The tremors in my hands and arms come and go, depending on how stressed I am.

MANN: Manofsky is a decorated serviceman, a weapons targeting specialist, a naval aviator who has also boated, skied and dived. Now he can't do any of those things.

Manofsky's problems began when he was sent to Kuwait in the run-up to the war in Iraq. Like thousands of others, he was given a drug called Lariam to prevent malaria. He got sick. He couldn't sleep and he started having psychological problems.

B. MANOFSKY: I lost it. I literally went nuts. I was talking to myself. I was talking to myself in the chow. I was waking up mad. I would go to bed mad. Using my hands to talk to myself.

MANN (on camera): You're wearing a military uniform and you're like one of those crazy people we see on the street.

B. MANOFSKY: Yes. I was (UNINTELLIGIBLE) I was getting ready to say.

MANN (voice-over): When he returned to the United States, his wife encountered a very different man.

TORI MANOFSKY, WIFE OF VICTIM: The panic attacks became so acute we had to rush him to the emergency hospital five different times. He also had went into seizures where his whole body was convulsing.

MANN: After civilian doctors determined his symptoms were related to his use of Lariam, Manofsky finally found a military doctor who also recognized the link.

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DR. MICHAEL HOFFER (ph), NAVY DOCTOR: It's usually more in this area here, and he's way down here.

MANN: Navy Dr. Michael Hoffer (ph) is treating him for a range of balance problems.

HOFFER (ph): Because Mr. Manofsky reported the Lariam exposure and did not report any other toxic exposure, we, again, with all medical likelihood, related it to the Lariam.

UNIDENTIFIED MALE: Lieutenant Commander Manofsky's dedicated leadership and professional expertise have been critical to accomplishment of this command's mission.

MANN: Mark Benjamin, an investigative reporter for UPI, has poured through hundreds of pages of records on Lariam and the people who have taken it.

MARK BENJAMIN, JOURNALIST: Soldiers in the field are handed Lariam routinely with no warning, no written warning, no verbal warning, and when they suffer the side effects, that's one of the reasons why they don't know.

MANN: The company that makes Lariam, Roche Pharmaceuticals, says it has been used safely by more than 20 million people. But Roche's literature warns users that in rare cases Lariam can cause hallucinations, suicidal thoughts, depression and paranoia. Roche would not provide a spokesperson on camera, but replied to CNN's questions in an e-mail.

"Roche has made Lariam medication guides available to the four pharmacy consultants for the services, who in turn send the information to military pharmacies."

Bill Manofsky says that information never made it to him.

Researchers have been raising their concerns about Lariam, known generically as mefloquine, for years in medical journals here in the United States and overseas. But it wasn't until this year that the assistant secretary of defense for health affairs ordered the military's own investigation.

DR. WILLIAM WINKENWARDE, JR., U.S. ASST. SECY. OF DEFENSE FOR HEALTH AFFAIRS: The bottom line is, if we can determine that there are serious adverse events that can be shown in a solid, scientific way, that is going to change our approach and our policy.

MANN (on camera): The Pentagon says it has told Congress at hearings that service personnel are warned about the side effects of this drug. Were you warned about the side effects?

B. MANOFSKY: No, I was not.

MANN (voice-over): Manofsky's 17-year military career is over. He's suing Lariam's makers and he's trying to get better. But in some ways, he may be luckier than other people who also took the drug.

Case in point, in the state of Colorado on March 14, a chilling call for help.

OPERATOR: (UNINTELLIGIBLE) County 9-1-1. What's the address of the emergency?

UNIDENTIFIED FEMALE: Parkdale Drive.

OPERATOR: OK. What's the problem? Tell me exactly what happened?

LAURA HOWELL, WIDOW OF BILL HOWELL: My husband just hit me and he's going downstairs to get his gun.

MANN: Bill Howell got his gun and used it. Minutes after the call, he shot himself in his front yard. Howell was a special forces officer who had returned home to his wife and children from duty in Iraq just three weeks earlier.

HOWELL: Bill's patriotism and devotion to his country and fellow special forces soldiers is beyond what most Americans are capable of comprehending. I would like Bill to be remembered for his 36 years of accomplishment and not final moments of impulsivity.

MANN: Laura Howell doesn't know why her husband did it. He had been drinking heavily. But Howell was also taking Lariam.

In North Carolina, families around Ft. Bragg wonder whether the drug had anything to do with a sudden surge in killings and suicides among the soldiers there in the summer of 2002. Among the cases, Master Sergeant William Wright, who confessed to killing his wife and later killed himself in jail while awaiting trial. He had taken Lariam during a deployment in Afghanistan.

The Army investigated the cluster of killings. It found that not all of the soldiers involved in the killings were taking the drug and concluded that Lariam was not the likely cause for the deaths.

Sue Rose is an activist who is trying to raise consumer awareness about Lariam.

SUE ROSE, CONSUMER ACTIVIST: The military is drawing the wrong conclusion from those deaths. I mean, the true group you want to look at are those men who took Lariam, and of the men who took Lariam, who also have been to Afghanistan, all three of them killed their wives and subsequently committed suicide.

MANN: Suicides among all the military personnel who served in Iraq and Kuwait last year were higher than in the military as a whole, but only a fraction of them were given Lariam and the Pentagon says it doesn't expect it will find a link.

WINKENWARDE: With respect to Lariam, we don't have any evidence that suggests that there is a tie-in between suicides and the use of the medication. We want to understand if there is. The absence of evidence does not prove that there is no relationship. We want to understand if there is, and that's why we're doing a study, to try to determine that.

(END VIDEOTAPE)

MANN: We take a break now. When we come back, more from the Pentagon about the people who took the drug and the policy to give it to them.

Stay with us.

(COMMERCIAL BREAK)

MANN: The U.S. Army has been fighting malaria since the first World War. But it was in Vietnam that it first encountered a drug resistant strain. That malaria attacked more U.S. soldiers than the Vietnamese did.

Welcome back.

Drug-resistant malaria is why the U.S. Army invented mefloquine, the drug known and sold as Lariam. But Iraq doesn't have drug-resistant malaria. In fact, most of the country doesn't have malaria at all. So even though thousands of Americans in Iraq and in Kuwait have been given Lariam, the Pentagon now says they probably don't need it.

The assistant secretary of defense who you saw a moment ago in my report said that in fact Lariam use will be cut back.

(BEGIN VIDEOTAPE)

WINKENWARDE: We thought we needed to use Lariam in Iraq because of the possibility of drug resistance and that strain of malaria that one would need to protect against by using Lariam, but we've determined that that type of strain of malaria is not something we need to worry about in Iraq, so we can use a drug called chloroquine.

So most of the people that were we think on the drug last year were in Iraq, so those numbers ought to be significantly lower this year.

MANN: Let me ask you flat out, is there a problem with Lariam?

WINKENWARDE: We don't have any evidence, scientific evidence, that there are serious adverse outcomes that would pose such a risk that we wouldn't want to use the drug. I think that's the key conclusion.

On the other hand, we have service members who have concerns and perceptions that there might be some adverse outcomes and we have a handful of anecdotal reports.

MANN: Why aren't soldiers, though, we talked about the FDA warnings. Why aren't soldiers being warned about what this drug can do to them in some circumstances?

WINKENWARDE: It's our policy that they receive the information. That's my policy. That's the Department of Defense policy. So that's our policy and we intend it to be practiced in every single situation.

MANN: Is it happening? Because our research suggests it's not happening. It suggests that a lot of soldiers are given this drug and have no idea that it's going to have any side effects whatsoever.

WINKENWARDE: Well, if that's true, that's not our policy, and that's not what we would want to happen.

As I had just indicated, we are redoubling our efforts to make sure that what in fact is our policy is what in fact is being done. I have -- any anecdote or report or concern otherwise is always something that we want to know about.

MANN: But would it be news to you? Forgive me. I say this with respect. You're the assistant secretary of defense for health affairs, and what we're hearing from everyone we've talked to is that soldiers have no idea what this drug

might be doing to them. And you're telling me that no one has ever mentioned that to you, that the soldiers are not getting the information?

WINKENWARDE: What you're telling me is something you've heard. It's a report from you. Perceptions and anecdote. I don't have any survey information. I don't have any hard information. I have not been presented with any information.

If you'd like to secure that information for me and bring it to my attention, I'd be glad to look at it.

MANN: Talking to you, I feel like I'm being unfair, and I'll tell you why. I'm asking you all of these questions about what it is the military is doing out in the field, and you seem to be answering me honestly and earnestly that the policy is of a particular kind. But what's happening out in the field is beyond you. It sounds like you don't know how this drug is being used and that when these concerns are being raised your best and most helpful answer is, "I need to have information."

Why don't you already have this information?

WINKENWARDE: We do have the information. We don't have information that suggests what you're saying. We have some information that would not suggest what you're saying.

MANN: Without reference to the policy, be very clear on that, are you telling me, for example, that military personnel who get this drug get information packets and medication guides with it? You're telling me that their medical records are complete when they're getting these drugs that they're being screened for these drugs when they enter the military, to make sure that those drugs are appropriate to them and they're being screened for these drugs when they leave the military, to make sure they haven't got adverse effects? Is that your factual understanding of what's happening?

WINKENWARDE: That's our policy. That's our approach.

MANN: Once again, forgive me for interrupting. I know what the policy is and you're being very clear about that. What I'm asking you is, do you know what is actually happening to the men and women who get this drug?

WINKENWARDE: Yes, we do.

MANN: And you are convinced the drug is going out only to the right people, they are being properly informed, as well informed as civilians are, and they're being screened for taking the drug to make sure they don't have prehistories, and to make sure when they leave the military they don't have problems and that it's being noted in their records?

WINKENWARDE: You're asking -- what I hear you asking is, how precisely are you executing against your policy standard, and what I can tell you based on the information that I have is that we're executing effectively against that policy standard.

Is it absolutely at 100 percent? Based on what you've told me, I would say it's not. But that's not our goal. That's not our policy. That's not our desired approach. And so we absolutely want to and intend in every way to use this medication appropriately, to give it out to where it's needed, to not prescribe it where it's not needed and to use it to save people's lives, to protect them from a lethal disease.

I want to make sure that we come back to that because, again, there are risks and benefits in anything that we do in medicine and healthcare, and so when we're dealing with a very real probability of individual -- not just an individual, but many individuals, contracting malaria, we have to take steps to protect them and use the best available medications and approaches that we have.

(END VIDEOTAPE)

MANN: We take a break now. When we come back, a public health expert with a different view of the drug.

Stay with us.

(COMMERCIAL BREAK)

MANN: Canadian troops also took Lariam in Afghanistan and before that deployed as peacekeepers in Rwanda and Somalia. Somalia was a turning point for the Canadian forces when one of its crack units became mired in the scandal over the torture and murder of a Somali prisoner. Several soldiers were tried but the prime suspect couldn't be. He suffered brain damage in a suicide attempt. His widow blames the Lariam that he and the others in his unit were given.

Welcome back.

The Canadian forces unit received Lariam once a week on a day they reportedly called Psycho Tuesday because of

the side effects they suffered. A Canadian government commission investigated the unit and the murder. It did not find a link with Lariam.

A short time ago we got in touch with the woman you saw in our report to talk about the questions that have been mounting around the world, apparently without the Pentagon knowing.

(BEGIN VIDEOTAPE)

ROSE: We have been looking at it since 1997. The Lariam action actually began in the United Kingdom in 1995.

MANN: 1997 and 1995 are a long way ago, nearly a decade ago in the United Kingdom. We've just heard from the assistant secretary of defense for health affairs who said that he's only just learned about the potential of the problem. He's not sure there's a problem. But the truth is, he doesn't know.

At this point in time, the year 2004, are you surprised that he's surprised? Is there the basis for some bigger suspicion than the one the U.S. government now has?

ROSE: I'm very surprised that he says he hasn't heard much about this. This has been the subject of much controversy abroad and here in the United States. There have been many articles in the scientific literature about it and lots of studies have been done.

The troops that went to Somalia in the early '90s were given this drug and had a horrible time with it. But unfortunately, most of them were misdiagnosed when they came home.

MANN: Let me ask you about that because we in fact just heard about that. There was a Canadian commission of inquiry into what Canadian troops did and took while they were in Somalia after that terrible torture and murder incident. That commission of inquiry didn't blame Lariam.

ROSE: That commission of inquiry didn't look at Lariam.

They were asked to by some of the doctors who were involved, but they said they didn't have time to look at it thoroughly, so it wasn't looked at.

MANN: Let me ask you about that in particular or in a more general sense, I guess. What the assistant secretary of defense for health affairs told us is that the evidence that has reached him has been anecdotal. It has been piecemeal. It has not been scientific and he wants science to prevail on this question.

So as someone who is both trained and teaching public health, can you tell us, has there been serious scientific work done on this question?

ROSE: Yes. There's been excellent scientific work done on this question. There were two studies, international studies, one published in 2001, which was a very large study, and another published in 2003, in which these studies were specifically designed to look at side effects from antimalarial drugs and to look at neuropsychiatric side effects.

And what they found in the study that was found in 2001 was that people taking Lariam had a 29 percent chance of having neuropsychiatric side effects. And what they found in the 2003 study was the rate of moderate to severe neuropsychiatric side effects went up to 42 percent. These are very high quality scientific studies. They're randomized, placebo-controlled, double-blinded clinical trials. You can't get a higher quality scientific study than the ones that have already been published.

MANN: And yet the Pentagon says it's going to undertake a study of its own. We have not heard about details of the study. Have you? Do you know anything about the kind of science the U.S. military is now planning?

ROSE: We've not heard any of the details of this study either. We're a bit concerned if they intend to rely on medical records, because it's our understanding that antimalarial medication is not recorded in service personnel's medical records. So we're concerned where they're going to actually get their data from.

MANN: Let me ask you more about what others have learned abroad. In addition to these scientific studies that you make reference to, are there organizations abroad? Are there other military organizations that have had experience with Lariam? Are there other American organizations for that matter that have had experience with Lariam?

ROSE: Well, starting with military organizations abroad, the Australian Army will not give Lariam to its troops. The United Nations will not give Lariam to its peacekeeping forces, and that decision is about a decade old. The British are extremely cautious with the use of Lariam, as are most of the other European countries. They know a lot more about it than the Americans do, obviously.

And in Iraq, our troops were the only troops taking Lariam. None of the other troops were taking Lariam because there was no need for that drug. That drug is active against a specific form of malaria that's not -- and its resistant to older drugs, older, safer drugs. But the malaria in Iraq is still sensitive to that drug. So there was no reason, and the Centers for Disease Control could have told the secretary of defense this, to be giving this drug at all.

MANN: Well, in fact, he conceded that to us and he said that far fewer people will be given that drug. But he made a point, and it seems like a reasonable one. If the U.S. military is sending men and women into harms' way, it has every interest in making sure that they are safe, in making sure that they are healthy and making sure that nothing that the Pentagon itself does makes them sick.

Why would the United States resist taking obvious steps if there were obvious steps to be taken away from a drug that was harmful?

ROSE: I don't understand that. There are good alternatives that are just as efficacious as Lariam with much fewer side effects. Maybe it's because the military, the Army actually invented this drug during the Vietnam War, and maybe they have a vested interest in something they invented. I don't know.

MANN: Just one last question for you. Why do so few people in the military know about this drug and despite your efforts know about the potential problems?

ROSE: Well, neuropsychiatric side effects are very hard to quantify, and one of the problems is that people, especially civilians, will get this drug from, for example, a travel doctor, and when they start to suffer mental problems, they don't realize that it could come from the drug. I mean, that's a very hard link for people to make unless they're specifically warned that this could happen. So they don't go back to the travel doctor. The circle is not connected.

In the military, the military men and women are trained to be tough, and so they're not going to be coming to their medics and complaining that they're having nightmares and they're having panic attacks and they're having anxiety, and if they don't know that they're taking a drug that could cause these problems, then for sure they're not going to be reporting these side effects.

MANN: So in theory, there could be a lot more people than any of us have heard of?

ROSE: Oh, we've just heard about the very, very tip of the iceberg. There are a lot of people out there. They are suffering. They don't know why they're suffering. And the doctors don't know why they're suffering either.

MANN: Sue Rose of Lariam Action USA, thank you so much for talking to us.

ROSE: Thank you.

(END VIDEOTAPE)

MANN: And that's INSIGHT for this day. I'm Jonathan Mann. The news continues.


END

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