

FDA Tests Find Squalene in Anthrax Vaccine

GOVERNMENT ADMITS BANNED SUBSTANCE EXISTS IN VACCINES, BUT
MAINTAINS IT DOES NO HARM

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After years of repeated obfuscation, the federal government finally admitted that a banned chemical additive linked to the Gulf War syndrome has been found in some of the vaccines developed to protect military personnel from biological attack.

This October, a spokesman for the U.S. Department of Defense (DoD) contradicted previous statements made by the government when he said that "trace amounts" of squalene were found in several lots of a vaccine used to protect troops from anthrax, a deadly infectious agent, during a recent series of tests by the U.S. Food and Drug Administration (FDA). However, he denied that squalene had been deliberately used in the making of the vaccine, saying instead that "it's not something that's been added to the vaccine that we give our troops."

A naturally occurring substance, squalene is produced by the liver to help metabolize cholesterol and combat physical injuries. It is found in shark liver oil, some vegetable oils, cosmetics and various nutritional supplements.

Since the 1980s, squalene has also been studied by the DoD and the National Institutes of Health as an adjuvant to boost the efficacy of certain vaccines. However, because animal studies have shown that squalene adjuvants may generate unwanted side effects, including autoimmune versions of arthritis, multiple sclerosis and other conditions, the FDA has never approved the general use of any vaccine containing squalene in the United States.

The safety of squalene as a vaccine adjuvant, and the possibility that it was used illegally on military personnel, were called into question last year when a professor at Tulane University conducted a study of more than 400 Gulf War veterans suffering from Gulf War syndrome (GWS) - a condition characterized by general fatigue, joint pain, memory loss, an inability to concentrate, and other ailments.¹ Ninety-five percent of those who exhibited symptoms of GWS had high levels of squalene antibodies in their blood. Many of the samples that tested positive for squalene were taken from soldiers who were not deployed to the Persian Gulf but still received the anthrax vaccine.

In a follow-up study published earlier this year, a Tennessee immunologist confirmed the findings of the Tulane study and concluded that the mysterious illnesses suffered by Gulf War veterans could have been caused by exposure to additives in vaccines.² This conclusion was vehemently contested by Pentagon officials, who maintained that squalene was never used in the making of the anthrax vaccine, and that even if it were present, it would not cause soldiers to become sick.

As early as this March, the FDA began releasing preliminary information stating that low levels of squalene had indeed been detected in some anthrax vaccines. In a written statement delivered during

congressional hearings into the safety of the anthrax vaccine on March 20, the FDA said that test results showed "squalene content was determined to be in a level of low parts-per-billion and was comparable to levels determined in three other lots of the anthrax vaccine."³

On September 28, the FDA released another report showing that trace amounts of squalene were found in five lots of the anthrax vaccine. The FDA did not make clear whether the lots that contained squalene were the same lots used to inoculate troops during the Gulf War, or whether they are being used in the current anthrax vaccination program. A spokesperson for the FDA also declined to comment on any potential health problems associated with the vaccine.

As late as this October, however, the DoD was still insisting that squalene "is not in the anthrax vaccine" and that the substance "has not been used in vaccines ... for a considerable period of time."³

On October 4, Pentagon spokesman Kenneth Bacon, speaking at a DoD news briefing, was asked about the FDA's licensure of the anthrax vaccine:

"Well, the anthrax vaccine has been used safely for 30 years," Bacon said. "It was approved for use in 1970 by the FDA. It remains a safe vaccine. All the lots we have administered to the troops have been approved by the FDA for release. So they have reviewed them, and what they've told us is that they have not found squalene in those lots."

When told by the news media of the FDA's announcement in March that squalene had indeed been found in several lots of anthrax vaccine, Bacon quickly put a halt to the briefing, excused himself, then returned several minutes later with "new" information.

"Apparently, my briefing book had not caught up to the science on squalene," Bacon said. "... A few minutes ago, I said the FDA had assured us that there wasn't (squalene in the anthrax vaccine). It turns out within the last month, the methods of discovering squalene have improved, and we've moved to be able to discover it."⁴

"We don't know whether those lots were administered to the troops," Bacon continued, "but the important thing is that it was not added. If it's in there, it's in there as a naturally occurring substance ... but it's not something that's been added to the vaccine that we give our troops."

While the exact amount of squalene found in the vaccines was termed "miniscule" by Bacon, the fact that any squalene was found was more than enough to irritate Representative Jack Metcalf (R-WA), an opponent of the military's mandatory anthrax vaccination program.

"We've been told for three years there is no squalene in the anthrax vaccine," said an exasperated Metcalf, "then suddenly we are told, 'Oh yes, it's there, but it's no big deal: it's everywhere.'"⁵

Bacon's statement has prompted the House Government Reform Committee to instruct the General Accounting Office to investigate, asking the GAO to determine how squalene got into the vaccine, how dangerous it might be to human subjects, and what research is being done to determine and combat any potential side-effects.

According to the latest figures from the American Gulf War Veterans Association, 487,098 members of the military have received at least one dose of the anthrax vaccine. Of those receiving at least one

dose, 1,152 people - approximately one in every 423 persons inoculated - have reported an adverse reaction.

A review by the Department of Health and Human Services earlier this year found that 592 cases were either "certainly" or "probably" caused by the vaccine, with 123 cases classified as "serious" and 10 requiring hospitalization due to an allergic or inflammatory response. Approximately 400 other personnel have either resigned from the military or faced disciplinary action rather than take the vaccine.⁶

References

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NOVEMBER 2000