

RESPONSE TO WILLIAM WINKENWERDER, M.D.

Assistant Secretary of Defense for Health Affairs

- 1. “Four separate and independent civilian panels have investigated claims of squalene in anthrax vaccine administered to our service members. All found the allegations without merit.”**

To which panels does Winkenwerder refer? If he means the Armed Forces Epidemiological Board (AFEB), the Institute of Medicine (IOM) and the National Academy of Sciences (NAS), they are civilian, but hardly independent. Since the late 1990s, all three have been staunch proponents of the second generation anthrax vaccine, which has been formulated with squalene since 1987. It was AFEB that solicited research proposals from military doctors for Operation Desert Shield because it presented “unique research opportunities.”

AFEB organized and funded many of the experiments conducted on U.S. military personnel over the past half century. AFEB also helped organized experiments on civilians too, even children. The infamous Willowbrook experiments, involving the injection of live hepatitis B virus into mentally handicapped children at the Willowbrook School in Staten Island, New York were organized by an AFEB director, Dr. Saul Krugman, and paid for by AFEB.

Testing oil adjuvants on troops has been done several times before at the recommendation of AFEB. The first time occurred at Fort Dix in New Jersey from 1951 to 1953. The Army then tracked these subjects for more than two decades with investigators, and with funding, from the National Institutes of Health, National Academy of Sciences-National Research Council and the U.S. Public Health Service.

With this kind of track record, it was troubling to discover that the National Institutes of Health formed a special working group in 1998 with the FDA and DOD to “fast-track” the licensure of the new vaccine. A year later, five lots of anthrax vaccine showed up “contaminated” with squalene.

So conflicts-of-interest abound here. AFEB, the IOM and the NAS have all endorsed research into “newer anthrax vaccines,” some of which happen to contain squalene. The NIH and FDA have been actively collaborating with the Defense Department to license the new vaccine. But no one from these agencies, not to mention Dr. Winkenwerder from DOD, has disclosed this to the public, let alone to military personnel.

- 2. “Moreover, we have conducted no experiments, as have been alleged, at Dover Air Force Base.”**

The former Wing Commander, Col. Felix Grieder, and the former chief pilot of the Reserve Squadron, Lt. Col. Jay Lacklen, have alleged that an experiment with

squalene added to anthrax vaccine took place at Dover Air Force Base in 1999. Senators Biden and Carper of Delaware have called for a GAO investigation into the matter. Given the Pentagon's track record of experimenting on troops and DOD's failure to disclose its seventeen year effort to replace the old anthrax vaccine with a new one containing squalene, I would argue that Winkenwerder's word alone on this matter cannot suffice.

When the National Institutes of Health formed a special NIH Working Group in 1998 to "fast track" the second generation anthrax vaccine, both the U.S. and British versions of the new vaccine contained squalene. A year later, in 1999, squalene was detected by the FDA in five lots of anthrax vaccine; then a DOD subcontractor found squalene in a sixth lot. In 2003, a British laboratory detected squalene in British-made anthrax vaccine intended for use in the second Iraq war.

3. "Further, we do not, nor does anyone else, add squalene to anthrax vaccine."

This is misleading. No one adds squalene to the licensed anthrax vaccine. That would be illegal. However, Army scientists at the United States Army Medical Institute of Infectious Diseases (USAMRIID) and the Walter Reed Army Institute of Research (WRAIR) have been adding squalene to various prototypes of the second generation anthrax vaccine since the late 1980s.

4. "Squalene is present naturally in the blood streams of healthy people at levels in the range of 250 parts per billion."

Squalene's alleged presence in the blood stream (Winkenwerder does not cite any references for this data) is precisely why it is so dangerous to inject this oil. Injecting squalene—an oil present in the blood stream and in neurological tissues—can initiate an immune response to this molecule, which, under normal circumstances, the immune system would otherwise ignore. This is an "autoimmune" response, a process in which the immune system attacks the constituents of the body that it is supposed to protect. Breaking the body's natural tolerance for one of its own molecules is not a good thing. Once primed to attack squalene, the immune system will attack it wherever it is found in the body. The immune system will not discriminate between what was injected and what was already in the body. If it's in the blood stream as Winkenwerder maintains, then this could result in inflammation of blood vessels and the autoimmune disease, vasculitis (which can cause blood clots). Squalene is found in neurological tissue and has been proven to induce multiple sclerosis and lupus in animals—both of which are diseases that result in neurological damage.

5. "In a study report, August 14, 2001, one of thirty lots of anthrax vaccine tested contained measurable levels of squalene. Three samples from that lot contained 9, 7 and approximately 1 parts per billion respectively."

This is true. But Winkenwerder conspicuously neglects to mention that in June 1999 the FDA tested five lots of anthrax vaccine and detected squalene in all five lots. What's more, the squalene concentrations were detected in a twofold serial dilution; these are a series of concentrations that double in volume from one lot to the next in order to establish the optimal dosage for a pharmaceutical ingredient.

There's a lot more that Winkenwerder isn't saying: like the fact that the House Committee on Government Reform issued a report in October 2000, censuring Winkenwerder's predecessor, Dr. Sue Bailey, for misinforming Congress on issues related to anthrax vaccine. If Congress couldn't take Sue Bailey's word at face value, why should we accept Winkenwerder's without checking his facts? The answer is we shouldn't. The committee also censured assorted Pentagon officials and Army scientists, including former Army Surgeon General Ronald Blanck, for misleading Congress about the presence of squalene in anthrax vaccine.

6. “The Food and Drug Administration told the U.S. Congress in Oct 2002 that any trace quantities of squalene detected in lab tests should be considered ‘naturally occurring and safe.’”

While the FDA's Dr. Mark Ellengold did suggest to Congress that the trace amounts of squalene the FDA found in the vaccine were “naturally occurring and safe,” he offered no data to support this. In making this assertion, Ellengold also made errors. He suggested that the “probable” source of squalene was the organism itself. Previous scientific analyses of the organism *Bacillus anthracis*, published in peer-reviewed scientific journals, have proven that it does not make squalene. This data is available in medical libraries across the country. Yet Ellengold did not correct his misstatement to Congress and Winkenwerder, perhaps unknowingly, is propagating Ellengold's error.

7. “To increase immune responses, as claimed in the articles, squalene would have to be present at a concentration at about one million times higher than found in lab tests; the concentration would be thirty million parts per billion.”

Chiron Corporation, which has been developing the squalene based vaccine additive, MF59, in close cooperation with the NIH and the Army has shown that it can initiate an immune response in animals with a minuscule squalene concentration of eighty-two parts per billion. The FDA detected an eighty-three parts per billion concentration of squalene in anthrax vaccine lot # FAV 047. This lot was administered at Dover Air Force Base. Tulane University Medical School has documented immunological responses to squalene in military personnel who were injected with as little as one dose of anthrax vaccine containing a squalene concentration of just 10 parts per billion.

Chiron makes a flu vaccine with squalene that is licensed in Europe, but not the United States. It was Chiron that had 48 million doses of its Fluvirin™ vaccine impounded at its British plant, and its license revoked, due to an unknown “contaminant.”

8. “Also, [squalene] would have to be present in combination with other chemicals in a form called an emulsion.”

This is precisely why another one of DOD’s other explanations for the presence of squalene in anthrax vaccine—that it rubbed off of someone’s fingers—is invalid. Squalene is found in sebum, a fatty substance secreted by glands in the skin. Everyone knows the expression “like oil and water,” which is commonly used to describe people who repel each other. That’s what squalene does with water; it repels water. It’s “hydrophobic.” It won’t mix with water unless you add detergents called surfactants (surface acting agents) to break the oil down. Surfactants are the “other chemicals” to which Winkenwerder refers.

Of course, this issue is somewhat moot because the BioPort workers who handled the vaccine—and the FDA scientist who analyzed five lots of vaccine for the presence of squalene—wore gloves. Their skin never came into contact with the vaccine.

9. “Importantly, the National Academy of Sciences’ Institute of Medicine in 2002 conducted a comprehensive review of anthrax [sic] safety and effectiveness.”

My book challenges the IOM conclusions about anthrax vaccine, and I’m not the first one to do so. GAO investigators disputed the IOM’s conclusions about the anthrax vaccine’s safety in its Survey of Guards and Reserve Pilots and Aircrew published in September 2002.

10. “We have a safe and effective anthrax vaccine to protect our forces.”

That’s only half correct. The licensed anthrax vaccine *is* safe. But U.S. Army scientists doubt its effectiveness. That’s why the Army has been trying to replace the old vaccine for the past twenty-five years.

— Gary Matsumoto —