

INFORMATION PAPER

DHA-IHD
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SUBJECT: Anthrax Vaccine and Long-Term Health Concerns

1. Purpose. To clarify facts behind anthrax vaccine rumors.
2. Facts.
 - A. The National Academy of Sciences (NAS) and its Institute of Medicine (IOM) released the most extensive review ever conducted of the science underlying anthrax vaccine on March 6, 2002. The comprehensive 265-page peer-reviewed report, entitled "The Anthrax Vaccine: Is It Safe? Does It Work?", examined the safety and effectiveness of the vaccine, evaluated the manufacturing processes, and discussed the future needs of the anthrax vaccine. The committee concluded that anthrax vaccine is as safe as other vaccines for adults. "The committee found no evidence that people face an increased risk of experiencing life-threatening or permanently disabling adverse events immediately after receiving AVA, when compared with the general population. Nor did it find any convincing evidence that people face elevated risk of developing adverse health effects over the longer term, although data is limited in this regard (as they are for all vaccines)."
 - B. Squalene. Squalene is a naturally occurring substance in plants, animals, and humans. It is an organic compound used for commercial purposes when derived from shark liver oil. It is found in a variety of foods, cosmetics, over-the-counter medications, and health supplements. The human body naturally contains about 250 parts per billion in the blood stream. Squalene is found on the surface of the skin (fingerprint oil), and squalene is a building block in the synthesis of cholesterol and steroid hormones. Research suggests squalene may increase oxygen transportation and boost the immune system as an antioxidant.(1)
 - C. Squalene in Vaccines. Squalene emulsions (MF59, AS03) have been used by some vaccine manufactures (Novartis, Ciba-Geigy, Chiron, Glaxo Smith Kline) as adjuvants in some influenza, tetanus, and diphtheria vaccines outside the USA to help stimulate an immune response. In 2016, the US Food and Drug Administration (FDA) approved FLUAD (an influenza vaccine containing the MF59 adjuvant) for use in the USA. The amount of squalene found in these vaccines is a million times greater than the traces found in a few lots of anthrax vaccine in the 1990s.(2,3)

- D. Squalene in Anthrax Vaccines. Studies by the FDA and Stanford Research International in 1999 identified trace levels of squalene, between 10 and 83 parts per billion, in anthrax (as well as diphtheria, tetanus) vaccines. These amounts were well below the concentration naturally present in human blood. These trace levels were thought to be due to contamination from fingerprints on lab glassware. Research groups stated "injecting trace amounts of squalene is unlikely to have any biological effect, given that it is already present in the body." In Congressional testimony in October 2000, an FDA official said the trace quantities of squalene detected were "both naturally occurring and safe."(4-6)
- E. Anti-Squalene Antibodies. A study in 2006 examined whether immunization with influenza vaccine containing MF59 would stimulate antibody responses against squalene. Blood samples were obtained pre-immunization and post-immunization from USA and European adults. Blood was also tested from unvaccinated adults. The researchers found anti-squalene antibodies were frequently in low titers in both healthy unvaccinated and vaccinated adults. Therefore, they concluded that MF59 emulsion adjuvant does not induce anti-squalene antibodies.(7)
- F. Anti-Squalene Antibodies and Health Effects. Although Tulane University researchers published concerns about anti-squalene antibodies found in some veterans who had received anthrax vaccine and who were suffering from "Gulf War Syndrome,"(8,9) other researchers have been unable to support these concerns, based on the information previously described.(1-7) To further address the concern that squalene in any quantity in a vaccine might be associated with long term disability, a 2009 study examined the relationship between anti-squalene antibodies and chronic symptoms reported by more than 570 Navy construction workers. The researchers found no association between squalene antibody status and chronic multi-symptom illness. They concluded that anti-squalene antibody status is unrelated to these health challenges.(10)
- G. Multiple other research studies on squalene have failed to find any association between squalene and chronic illness. US public health authorities and the World Health Organization have concluded that squalene-adjuvanted vaccines are safe.(11) The US Department of Defense appreciates that there remain many unanswered questions regarding the causes of some chronic illnesses. However, evidence does not support any association between chronic illness and intentional or unintentional addition of squalene to any vaccines

3. References.

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