

John C. Carleton

American by Birth, Southern by the Grace of God

Judge orders DoD to stop requiring anthrax shots

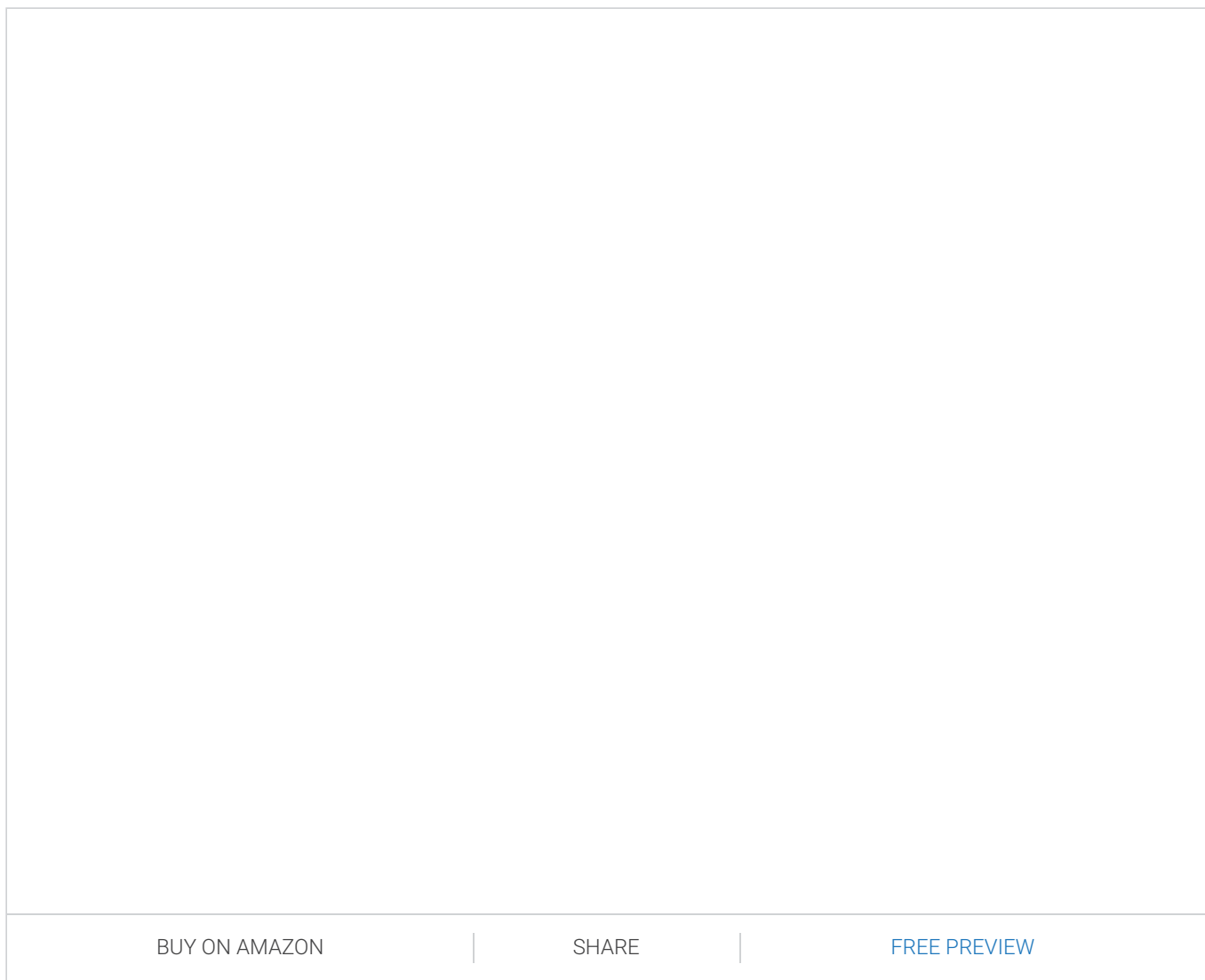
VACCINE • A

THE COVERT GOVERNMENT EXPERIMENT
THAT'S KILLING OUR SOLDIERS

and Why GI's Are Only the First Victims



GARY MATSUMOTO



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Dec 23, 2003 (CIDRAP News) — Stating that US soldiers should not be used as “guinea pigs for experimental drugs,” a federal district judge in Washington, DC, yesterday granted a preliminary injunction against the Department of Defense’s (DoD’s) mandatory anthrax vaccination program.

US District Judge Emmet G. Sullivan concluded that Anthrax Vaccine Adsorbed (AVA) has never been specifically approved or labeled for use against inhalational anthrax, the main aim of the military vaccination program, as opposed to skin anthrax. Consequently, service members should not be vaccinated without their informed consent or a presidential waiver of the informed-consent requirement, he said.

“This court is persuaded that AVA is an investigational drug and a drug being used for an unapproved purpose,” Sullivan wrote.

“The women and men of our armed forces put their lives on the line every day to preserve and safeguard the freedoms that all Americans cherish and enjoy,” the judge stated. “Absent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs.”

AVA is given in six doses over 18 months, with annual boosters thereafter. Close to a million military personnel have received anthrax shots since DoD launched the current immunization program in 1998, according to BioPort Corp., current manufacturer of AVA (now called BioThrax). Hundreds of soldiers have quit the military or sought transfers to other units to avoid the shots, and some have been disciplined or court-martialed for refusing them.

In defending against the lawsuit, DoD officials said there have been 105 serious adverse events among 830,000 anthrax vaccinees, according to Sullivan’s ruling. The document says that the vaccine label lists an overall adverse-event rate of 5% to 35% and that six deaths have been blamed on the vaccine. In addition, according to the ruling, the vaccine’s risk classification for pregnant women has been raised from category C, meaning risk can’t be excluded, to category D, positive evidence of risk.

Plaintiffs seeking to halt the Anthrax Vaccine Immunization Program (AVIP) include members of the regular military and the National Guard, plus some civilian contract employees of DoD, according to the court ruling. Three of the six plaintiffs have already had anthrax shots.

Sullivan ordered the defendants, who include DoD, the Food and Drug Administration (FDA), and the Department of Health and Human Services, to file responses to his ruling by Jan 30, 2004. Little information was available today on DoD’s immediate reaction to the injunction. But a New York Times report said the Justice Department was reviewing the decision. The story quoted Pentagon officials as saying it was not clear if DoD will have to stop inoculating military personnel while legal proceedings continue.

The court ruling says that AVA was originally licensed by the National Institutes of Health in 1970. The FDA later took over licensing of drugs and reviewed the safety, effectiveness, and labeling of all approved drugs. In 1985 a panel of experts who reviewed AVA determined that it was “safe, effective and not misbranded,” according to the ruling. However, the panel found that the vaccine’s efficacy against inhalational anthrax was not well documented, because in the main

clinical trial of the vaccine among mill workers handling goat hair, very few cases of inhalational anthrax occurred.

Subsequent events never provided a clear legal justification for using AVA to prevent inhalational anthrax, according to Sullivan's ruling.

In 1995 the Army proposed a plan to expand the vaccine's indications to include protection against inhalation anthrax, he wrote. The following year, the Michigan Department of Public Health, which then manufactured the vaccine, filed an investigational new drug (IND) application with the FDA, seeking permission to conduct clinical trials to support a change in the labeling. "The IND application is still pending and, to date, there is no indication for inhalation anthrax on the label or on the package insert," Sullivan wrote.

However, DoD lawyers argued in the case that the IND application was filed as a result of a "dispute between underlings" and is no longer being pursued, though it is technically still pending.

In 1997 DoD officials sought FDA confirmation that the vaccine was licensed for inhalational disease. In response, the FDA deputy commissioner wrote that the DoD's view that the license indeed covered inhalational anthrax was "not inconsistent with the current label."

However, Sullivan concluded that the FDA "has failed to provide a formal opinion as to AVA's investigational status." Further, no additional studies have supported the vaccine's efficacy for inhalation anthrax, and the label does not list that indication, he wrote. Moreover, sealed documents indicate that the IND application is still pending, and some DoD statements suggest that DoD itself has sometimes viewed AVA as experimental in relation to inhalational anthrax, he added.

"Given all these factors, the Court would be remiss to conclude that the original license included inhalation anthrax," the judge stated. He concluded that the mandatory vaccination program "amounts to arbitrary action."

The ruling notes that Congress in 1998 forbade DoD to require troops to take INDs or drugs not approved for the intended use without the troops' informed consent. Congress stipulated that only the president could suspend the consent requirement. The law was a response to concerns that INDs used during the 1991 Gulf War might have caused mysterious illnesses in veterans.

The government argued that requiring informed consent for the anthrax shots would essentially stop the vaccination program for forces in Iraq and in the war on terrorism and could hinder overall military readiness. But the plaintiffs, according to the ruling, responded that if the risk of anthrax attacks was so high, the US State Department and the British and Australian military commands in Iraq would have vaccinated their personnel.

Sullivan said he was “not convinced that requiring the DoD to obtain informed consent will interfere with the smooth functioning of the military.” But if that did happen, he wrote, DoD could seek a presidential waiver of the requirement.

Sullivan’s ruling does not refer to the recent 17-month study of AVA by the Institute of Medicine. In that study, released in March 2002, experts concluded that the vaccine was “acceptably safe” but called for development of a new vaccine that requires fewer doses and causes fewer reactions. After reviewing the evidence from human and animal studies, the panel said the vaccine is effective against anthrax, including the inhalational form.

SOURCE:

<https://www.cidrap.umn.edu/news-perspective/2003/12/judge-orders-dod-stop-requiring-anthrax-shots>

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