Victims of vaccine?

N.C. troops say military program is unsafe

ELIZABETH LELAND

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Two days after a military nurse injected Lavester Brown with the anthrax vaccine at Pope Air Force Base near Fayetteville, his heart failed. Brown was 34, an avid athlete, career military. Doctors had warned him to avoid vaccinations, he said, because of a reaction to a malaria drug in the early '90s. But when Brown told superiors, he said, they warned he could be kicked out of the military if he didn't get vaccinated for anthrax.

Brown was afraid: of the vaccine, of losing his job. He had a wife and four young children to support.

"I kept telling them, `I can't take the shot.'"

The vaccination is mandatory, part of the military's war on terrorism. Brown had been in the Air Force 14 years and was trained to follow orders. So when a commander, a major, a captain and a first sergeant all ordered him to be vaccinated, Brown, a technical sergeant, rolled up his sleeve and took the jab.

He is now awaiting a heart transplant.

Thousands of soldiers have suffered unexplained illnesses after getting the anthrax vaccine, ranging from muscle aches to death. The federal Food and Drug Administration says the vaccine has no more side effects than other vaccines, but cases like Lavester Brown's raise troubling questions:

Is the vaccination safe?
Should the military require troops to take it?

There was concern about the anthrax vaccine long before the threat of global terrorism.

In the 1990s, the FDA found problems with quality control procedures at the only U.S. company that makes the vaccine, then owned by the state of Michigan. The FDA warned that if the problems were not corrected, the company could lose its license. The state halted production in 1998 and began renovations, then sold the plant to BioPort.

After terrorists hijacked planes on Sept. 11, 2001, and anthrax-laced letters killed five people and infected at least 13 others, demand for a vaccine erupted. In January 2002, the FDA gave BioPort approval to distribute its vaccine to the military.

The FDA and the Department of Defense and BioPort all say the vaccine is safe. A vocal group of current and former military personnel, doctors and members of Congress claims it is not. Three lawsuits challenging the vaccine are now in federal court.

To the emergency room
Brown knew nothing of the controversy on Friday, Feb. 27, when he got the fourth in a series of six anthrax shots. He rarely got sick, not even a cold. He didn't drink. He didn't smoke. He stood 5 feet 11 1/2 inches and weighed 207 pounds, but so much was muscle, he looked lean.

The day after the fourth anthrax shot, Saturday morning, he played basketball at the gym as usual but quickly tired. He went to the emergency room that night, he said, and a military doctor diagnosed a gastrointestinal infection.

By Sunday, he felt as if his body was filling up with fluid. The muscles in his neck throbbed and bulged. He had trouble breathing. Back at the emergency room that night, he said, a doctor again diagnosed gastrointestinal infection.

"Something else is happening," Brown remembers saying. "I can't breathe."

He said his wife, Ebony, insisted on X-rays. "When they looked at the X-rays," Brown recalled, "the doctor got this look on his face. I knew something was terribly wrong."

Brown said his heart was so enlarged, it had almost stopped pumping. He now takes medication to keep it beating until a transplant becomes available. He has dropped to 151 pounds, and walking only a few feet exhausts him. Friday, he was medically retired from the Air Force.

Before he got sick, Brown sometimes worked two jobs to provide for Ebony and their four children, ages 5 to 12. Now Ebony works and the children help care for him, and that's been a tough transition.

"I wish we had done our homework before Lavester got in line (for the vaccine)," Ebony said. "We trusted the military."

Mandatory shots

Until recently, anthrax had been considered primarily a livestock disease. People can be infected in three ways -- through skin contact, by eating infected meat or by breathing airborne spores -- but it's rare.

The military became convinced that Iraq had developed biological weapons, including anthrax, and might pack its Scud missiles with the deadly bacteria. Nearly everyone who inhales anthrax dies if not treated.

In 1998, the Defense Department made vaccinations mandatory.

Since then, about 1.2 million military personnel have received the vaccine, six doses over 18 months, followed by yearly boosters. (Several hundred thousand, a Pentagon spokesman said, got the vaccine during the 1991 Persian Gulf War.)

Out of 4.7 million doses given since 1998, the government says it has received 3,817 reports of adverse reactions, from headache, fatigue and fever to cancer, cardiac arrest and autoimmune diseases. The reaction rate, the government says, is about the same as for other adult vaccinations.

Studies have reached conflicting conclusions.

The Pentagon cites a 2002 report by the Institute of Medicine, a private, nonprofit scientific group, that said a better vaccine is needed, but that the current vaccine is "acceptably safe and effective."
Other studies link the anthrax vaccine to Gulf War illness, a medically unexplained fatigue suffered by veterans of the first Gulf War. One study found more adverse reactions to the anthrax vaccine than to other vaccines, and urged doctors to report all reactions so the scope of the problem could be determined.

Many cases, critics say, still go unreported.

Dead at 29

Christine Nilson, who lives in Wilmington, hadn't heard about the controversy over the anthrax vaccine until after her husband, Erik, died. Now she's convinced it killed him.

Erik Nilson flew CH-46 helicopters for the Marine Corps and was vaccinated twice, before two separate six-month deployments to the Mediterranean.

Soon after he came home for the second time, in October 2001, Christine noticed the whites of his eyes had yellowed. Doctors at Walter Reed Army Medical Center in Washington discovered bile duct cancer, a slow-moving, usually fatal cancer that most often attacks people over 60.

Nilson was 29 and had a 2-year-old son, Luke.

He was, Christine said, "a man's man," who loved hunting, fishing and the Marines. He had had a rough childhood, she said, and often told her he wanted nothing more than to be a good father.

Six months after the cancer was discovered, Erik Nilson died.

Christine Nilson said no one from the military ever mentioned a possible connection with the anthrax vaccine. The national Vaccine Adverse Events Reporting System has no record of Nilson's death.

But the more Christine Nilson read, the more she believed there was a connection.

"There is," she said, "no other explanation for it."

Rapid-acting diseases

Other service members have died of rapid-acting diseases after getting the vaccine, including Army cook Sandra Larson of Kansas. Four weeks after her sixth anthrax shot, she was diagnosed with aplastic anemia, a rare disorder resulting from failure of bone marrow to produce blood cells.

She died two months later. She was 32.

The package insert on the vaccine, approved by the FDA in 2002, cites her death and the deaths of five other vaccinated military members. But a panel of civilian doctors concluded that none of the deaths was related to the vaccine.

The Pentagon has linked only one death to the vaccine: Rachel Lacy, a 22-year-old Army reservist, who died in April 2003 of a pneumonia-like illness after receiving five vaccines, including anthrax. The Pentagon said the vaccines may have triggered the illness that led to her death, but that "the evidence was not conclusive."

Critics say the government is stonewalling the way it did with the herbicide Agent Orange in the Vietnam War and with Gulf War illness.
"The first thing they do is fight, deny, obfuscate ...," said Steve Robinson, executive director of the National Gulf War Resource Center, an advocacy group for veterans. "Meanwhile people are getting sick."

About 10,000 Vietnam veterans receive disability benefits because of exposure to Agent Orange, and tens of thousands of others suffer illnesses. An estimated 100,000 Gulf War veterans suffer a range of symptoms, including memory and thinking problems, fatigue, joint pain, depression, anxiety, insomnia, headaches and rashes.

No proof, no medical help

Robinson said he has spoken with hundreds of veterans who said they had adverse reactions to the anthrax vaccine, but they can't prove it and are not getting the medical help they need. They complain of chronic fatigue, bone and muscle pain, migraine headaches, short-term memory loss and cognitive impairment."While anthrax is a threat," Robinson said, "the American public, much less the military, should not be given an inferior vaccine."

Meryl Nass, an internist in Bar Harbor, Maine, who has testified before Congress about the vaccine, said she has treated dozens of soldiers and corresponded with thousands more.

"I've seen so many people with the exact same thing, the same story," she said. "They can't think straight. They have pain in different parts of their bodies ... and they're fatigued." Usually, she said, they have something else wrong, too: multiple sclerosis or lupus or a sleep disorder.

As a doctor, Nass said, the last few years have been an emotional roller coaster "watching 1 million be vaccinated when I knew at 100,000 what was happening."

Forced vaccinations

In federal court, two lawsuits are pending against BioPort, a third against the Food and Drug Administration, the Defense Department and the Department of Health and Human Services.

The lawsuits challenge whether the vaccine is safe, effective, even necessary.

On Dec. 22, 2003, U.S. District Judge Emmet Sullivan in Washington, D.C., blocked the Pentagon from forcing soldiers to get vaccinated. He ruled that the FDA had never approved the vaccine for use against inhaled anthrax. The military, he said, could not make troops "serve as guinea pigs for experimental drugs."

Eight days later, the FDA approved the vaccine against inhaled anthrax.

Although Sullivan called the timing of the order "highly suspicious," he lifted his injunction.

The military once again ordered vaccination.

Refusal, court-martial

As many as 500 active-duty personnel have been dismissed from the military for refusing vaccination, according to congressional testimony. At least 100 have been court-martialed. Tom Kaufmann, an airman first class at Seymour Johnson Air Force Base in Goldsboro, refused to be vaccinated in December 2002.

He had read about problems at the manufacturing plant, he said, as well as about illnesses among people who got the vaccine.

Kaufmann, now 22, was demoted, then discharged under "conditions other than honorable."
"My first sergeant repeatedly called me a coward, saying I was afraid of war, afraid of serving my country," Kaufmann recalled. "I told them that I wanted to deploy. I wasn't against the war."

He was, he said, only against the vaccine.

• Anthrax comes from the Greek word for "coal" because infected skin forms ugly black lesions.

• The rod-like bacteria were discovered in the 19th century. Louis Pasteur created the first vaccine in 1881.

• Anthrax spores can live in soil for decades. People contract the disease in three ways: through skin contact, eating infected meat or breathing airborne spores.

Most Common Adverse Reactions
erythema, headache, arthralgia, fatigue, fever, peripheral swelling, pruritus, nausea, injection site edema, pain/tenderness and dizziness.

Less Frequent Adverse Reactions
cellulitis, cysts, pemphigus vulgaris, endocarditis, sepsis, angioedema and other hypersensitivity reactions, asthma, aplastic anemia, neutropenia, idiopathic thrombocytopenia purpura, lymphoma, leukemia, collagen vascular disease, systemic lupus erythematosus, multiple sclerosis, polyarteritis nodosa, inflammatory arthritis, transverse myelitis, Guillain-Barré syndrome, immune deficiency, seizure, mental status changes, psychiatric disorders, tremors, cerebrovascular accident (CVA), facial palsy, hearing and visual disorders, aseptic meningitis, encephalitis, myocarditis, cardiomyopathy, atrial fibrillation, syncope, glomerulonephritis, renal failure, spontaneous abortion and liver abscess. Infrequent reports were also received of multisystem disorders defined as chronic symptoms involving at least two of the following three categories: fatigue, mood-cognition, musculoskeletal system.

Fatalities
cardiac arrest (2), myocardial infarction with polyarteritis nodosa (1), aplastic anemia (1), suicide (1) and central nervous system lymphoma (1)

SOURCE: FDA-approved package insert for anthrax vaccine

Elizabeth Leland: (704) 358-5074; eleland@charlotteobserver.com.
Concluding that the FDA violated its rules by approving the vaccine late last year, U.S. District
Court Judge Emmet Sullivan said the mandatory vaccination program, which has inoculated more
than 1.2 million soldiers since 1998, is “illegal.”

Sullivan wrote that his ban on involuntary vaccination will remain until the FDA reviews the
anthrax vaccine properly or until President Bush determines the normal process must be waived
because of emergency circumstances.

The Defense Department has required many soldiers serving in Iraq and Afghanistan to be
vaccinated and has punished those who refused. The department expanded its anthrax and
smallpox vaccination programs in July to include troops stationed in Korea and other areas in
Asia and Africa, despite complaints from some soldiers that the vaccine made them sick.

In a statement, the Defense Department said it will stop giving the vaccine while reviewing the
decision. It said it believes the anthrax vaccine is safe and effective.

In his decision, Sullivan wrote that the FDA’s approval was invalid because it did not meet
required review standards and failed to seek the necessary public comment.

Carolina Connections

After Gail Dunlap of Charlotte heard about the ruling, she exclaimed, "I'm absolutely ecstatic."

Her husband, Russell, 42, a sergeant at Fort Bragg, suffered strokes, headaches, memory loss,
joint pain, violent mood swings and developed diabetes after getting the anthrax vaccine.

Their daughter, Crystal, 17, begins basic training at Fort Jackson, S.C., Nov. 7. The couple
worried that she, too, would have to take the vaccine. "There's nothing I can do about Russell,"
Gail Dunlap said, "but, oh, my God, Crystal's saved."

The Observer reported on the controversy Sept. 26 in a story that featured Lavester Brown,
whose heart failed in February after getting the mandatory vaccine. Brown, 34, who had been
stationed at Pope Air Force Base near Fayetteville, underwent a heart transplant Tuesday night
and was listed Wednesday in stable condition.

elizabeth leland