

Pentagon unable to back claim of three-shot anthrax shield

By Rick Maze
TIMES STAFF WRITER

The Defense Department is dropping its claim that service members are protected from the deadly anthrax disease after receiving just three of the required six vaccinations.

Under fierce questioning from members of the House Government Reform Committee at an Oct. 12 hearing, defense officials could provide no scientific evidence to back what they have been telling troops.

"It may very well be we have made a statement we should not have," said Marine Maj. Gen. Randall L. West, special assistant for anthrax and biological warfare to the undersecretary of defense for

personnel and readiness. "We will take that statement off."

Lawmakers seized upon West's statement as a further example of why the Pentagon is having trouble convincing some service members that the six-shot series of inoculations — ordered last year for all active and reserve members — is safe and effective.

Kathryn C. Zoon, director of the Food and Drug Administration's Center for Biologics, Evaluation and Research, further hurt the Pentagon's credibility by saying the FDA would not have permitted a vaccine manufacturer to make a similar claim about the efficacy of just three anthrax shots unless more research had been done. The FDA, she noted, has no power over

the Pentagon's use of the vaccine or its claims.

West, former deputy commander of the II Marine Expeditionary Force, recently was reassigned to the Pentagon to bolster the credibility of the year-old vaccination program. He is convinced vaccination against anthrax is "the right and responsible thing," he said.

Inhalation anthrax, an aerosol version of the bacterial disease, is the most deadly form and therefore most likely to be used by an enemy in a biological weapon. Military officials say it is at least 95 percent fatal if untreated, which is one reason it's so high on the list of biological warfare agents.

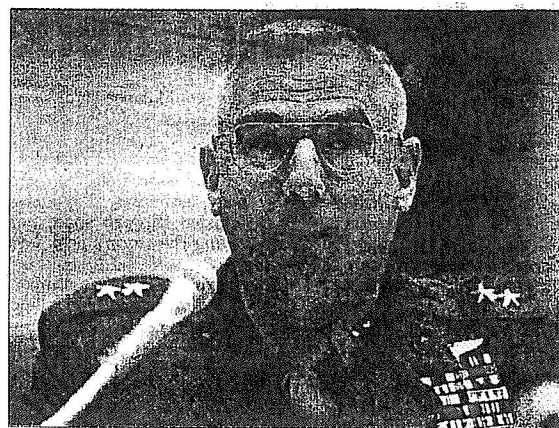
The United States recently learned that Iraqi troops had anthrax available for use during the Persian Gulf War, West said. If it had been used, "we would not have been ready" and many U.S. service members would have died, he said.

But even after the Pentagon has given more than 1 million vaccinations — and with millions more to come — doubts continue to grow about how much thought went into the decision to vaccinate all military personnel.

GAO in the fray

The General Accounting Office, the investigative arm of Congress, fueled those doubts with its testimony Oct. 12. Kwai-Cheung Chan, director of special studies and evaluations in the national security division of the congressional watchdog agency, said he could find no scientific studies outlining what the proper dosage of the vaccine should be. He also could not find studies showing that the six-shot regimen, with annual booster shots, ordered by the Pentagon is the right amount. It could be too little or too much, Chan said.

Preliminary results of an Army study being conducted at Tripler



TIM LOEHKE, TIME

"It may very well be we have made a statement we should not have," Marine Gen. Randall L. West, with the Defense Department, said about an earlier claim that three inoculations could protect a recipient against anthrax.

Army Medical Center in Hawaii, show reasons for concern about the dosage, Chan said. That study, focusing on the prevalence, duration and severity of short-term health problems due to vaccination, shows women report more adverse reactions than men, he said. Further, there are no studies on the long-term safety of the vaccine, although people who handle animals have been vaccinated against anthrax since the 1950s, Chan said.

Defense officials claimed that service members who received the first three doses of the vaccine — taken over four weeks — would be protected. But they based that claim on animal studies conducted in the 1950s. Chan said a different vaccine was used in those tests. The ideal dosage was increased to six shots after three people who had been vaccinated became infected after they were exposed to anthrax, he said. That study looked at cutaneous anthrax, a form of the bacteria that infects the skin, not the aerosol that would be in a weapon, Chan said.

The vaccine's manufacturer, BioPort Corp. of Michigan, asked the Food and Drug Administration last year to consider reducing the

required shots to five, he noted. Sue Bailey, assistant deputy secretary for health affairs, the Tripler study's findings show men and women react differently to the vaccine, she said. One theory, she said, is women have a stronger immune response to the vaccine, which would result not only in more adverse reactions but also in stronger and quicker protection, she said.

Lawmakers included a provision in the 2000 defense appropriations bill ordering two independent studies that will investigate some of the unanswered questions.

One study, to be conducted by the General Accounting Office, looked at potential morale problems caused by the vaccination program, including whether it is interfering with recruiting and retention. Investigators also will examine the threat that such weapons would pose against U.S. troops and military programs for determining whether there are health risks associated with vaccination.

A second study, by the National Research Council, will look at the vaccine's effectiveness and safety. It will look at the type and severity of reactions, including gender differences. □

VACCINATIONS AND GENDER

Women are more likely than men to report an adverse reaction to the anthrax vaccination, according to preliminary survey results at Tripler Army Medical Center, Hawaii. The center tracked reactions within a test group of 471 men and 83 women who received anthrax shots over the past two years. A higher percentage of women than men missed duty because of the shots.

| Reaction | 1st dose | | 2nd dose | | 3rd dose | | 4th dose | |
|------------------------------|----------|-------|----------|-------|----------|-------|----------|-------|
| | M | F | M | F | M | F | M | F |
| Moderate to severe redness | 17.5% | 49.1% | 17.2% | 46.9% | 17.2% | 39.8% | 31.6% | 39.8% |
| Swelling in lower arm | 9.7 | 13.4 | 9.5 | 13.5 | 9.2 | 13.0 | 7.1 | 8.4 |
| Pain limiting elbow motion | 9.7 | 17.1 | 8.7 | 13.5 | 7.6 | 11.7 | 7.9 | 8.6 |
| Localized itching | 25.2 | 62.6 | 25.7 | 60.4 | 24.5 | 57.9 | 27.7 | 39.2 |
| Lump or knot | 63.9 | 89.9 | 64.4 | 87.8 | 60.5 | 83.6 | 65.5 | 73.2 |
| Muscle soreness | 66.6 | 79.7 | 64.7 | 76.4 | 61.8 | 70.8 | 60.4 | 61.6 |
| Needed outpatient treatment* | 5.3 | 10.0 | 2.0 | 13.8 | 2.7 | 3.9 | * | * |
| Missed duty* | 2.2 | 5.0 | 2.0 | 5.1 | 0.9 | 3.9 | * | * |

*Data not available

SOURCE: GENERAL ACCOUNTING OFFICE TESTIMONY BEFORE HOUSE GOVERNMENT REFORM COMMITTEE
ATPCO

Crowe denies vaccine became mandatory to benefit him

By Rick Maze
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A former chairman of the Joint Chiefs of Staff who now is director of the company that produces the anthrax vaccine denied Oct. 12 that the military's mandatory vaccination program was in any way a repayment for his years of military service.

Retired Navy Adm. William J. Crowe Jr., who served as chairman of the Joint Chiefs from 1985 to 1989, went on to become U.S. ambassador to Britain from 1994 to 1997. The Pentagon's decision to require all service members to be vaccinated occurred months before

he owned a piece of BioPort Corp., the Michigan pharmaceutical company that is the nation's only producer of the anthrax vaccine.

"I never — repeat, never — solicited any official of this administration to install or promote a mandatory inoculation program," Crowe told members of the House Government Reform Committee. "If this charge were not so ridiculous, it would be offensive. It outrageously exaggerates my influence. I did not have that much influence when I was chairman, and I certainly do not have it now."

Defense Secretary William Cohen announced the mandatory

vaccination policy May 18, 1998, after months of study by a Pentagon steering group. At the time of the announcement, BioPort was owned by the state of Michigan, which was trying to sell the firm. An investment group that included Crowe was among several active bidders. Michigan did not announce the Crowe group had been selected until June, after the Pentagon decision.

Crowe said the Defense Department did not pull any strings to help his investment group win the bidding. "The Department of Defense maintained a neutral position," Crowe said. Any suggestion

that there is a link between his military service and the Pentagon's decision is "pure fantasy," he said.

While there is no evidence of featherbedding to help Crowe, Rep. Dan Burton, R-Ind., the committee's chairman, said it is clear the Pentagon is pouring money into the firm. The Defense Department provided \$18.7 million for plant improvements and agreed to pay \$10 per dose of vaccine, up from the previous cost of \$2.50 a dose. Each service member receives six shots in the course of the vaccination.

Rep. Christopher Shays, R-

Conn., said he understands the Pentagon would want to be the only supplier of the vaccine. "Basically, this is a military operation," he said.

But Shays wondered why the Pentagon did not put a lien on BioPort assets to secure its investment. Defense officials did reply directly to Shays' question but said the money provided by the Pentagon is intended to improve production facilities.

Defense officials also said they have not written BioPort a check. Marine Maj. Gen. Randall L. West, the Pentagon's special assistant for anthrax and biological warfare, said that while the price per dose has increased, "we are paying the price they asked for