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A shot in the dark

The U.S. military requires troops to take controversial anthrax shots and court-martials them if they refuse. But critics say the vaccine is too dangerous -- and with Saddam's bioweapons nowhere to be found, needless.

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Dec. 10, 2003 | This summer, on the first Monday of August, Teresa Colunga was taking a break from her job at the local bakery in Bellville, Texas, a town of 4,000 people 60 miles west of Houston, when a local patrolman approached and told her the police station had received a fax from the Army about her big brother, 20-year-old Zeferino, an American GI serving in Iraq. The note said he had been transferred to a hospital in Landstuhl, Germany, where he was being treated.

Shaking with anxiety, Teresa thought back to the letter Zeferino wrote her in May when he first arrived in Kuwait and told her he was fighting a 102-degree fever. "But he never felt much of it. He figured, I'll just beat it," she recalls. "That's the kind of boy my brother was." It wasn't until weeks later that Teresa found out from friends stationed with her brother that for the entire month of July he had complained of chest pains and a swollen spleen and sought medical attention. Army medics, she says, diagnosed him with tonsillitis.

That sickbed image didn't jibe with the Zeferino she knew -- 6 feet tall and 220 pounds "of pure muscle" with the nickname "Cowboy." A regular blood donor, he played on the high school football team and was also a member of the National Honor Society -- one reason Teresa says Army recruiters literally followed him around town, trying to land a commitment. Zeferino signed on for duty his senior year in high school.

Just days before the fax, on Aug. 2, Teresa had an inkling something might be wrong when her brother failed to call his father on his birthday. "My brother loved and respected my dad and would never forget," says Teresa.

Teresa asked the policeman to call the hospital in Germany and find out what was wrong. "After he talked to the nurse, he looked at me and said, 'Your brother has cancer, leukemia.' I said, 'There's no way.'" When Teresa relayed the news to her mother, Juanita Colunga fainted on the spot.

Two days later, after contracting pneumonia, Zeferino died from a 105-degree fever, says Teresa.

After receiving three different explanations for his death (acute leukemia, acute lung injury, and pneumonia), members of the Colunga family are still awaiting their copy of the final autopsy. There are a lot of questions they want to ask. Most of them are about a topic the Army doesn't seem to want to discuss: the series of anthrax vaccination shots Zeferino received right before he was deployed to the Persian Gulf.

For years, critics inside and outside the government have argued the vaccine is too dangerous. They say it causes far too many adverse reactions -- cases in which, instead of boosting the immune system, the vaccine triggers a violent and sometimes deadly physical reaction. They charge that the military is forcing troops to take the shots to prove their loyalty, or for political

reasons, despite the fact, they say, that they have not been proven to be safe enough. And they question whether the shots are even necessary.

The Department of Defense and the civilian [Centers for Disease Control](#) insist the shots are safe and that the adverse reaction rate is comparable to that found with other types of vaccines. To date, the military has given the vaccine to almost a million troops.

"The anthrax vaccine is probably one of the safest and most studied vaccines there is right now," says James Turner, a Department of Defense spokesman. "Unfortunately, there are side effects with all vaccines." (Last month, the Pentagon [conceded](#) the vaccine might have killed a soldier who died of pneumonia-like symptoms in April. Click here for [her story](#).)

What makes this debate more than a mere intellectual exercise is that all members of the U.S. military serving in Operation Iraqi Freedom, as well as the 100,000-plus troops set to rotate into the region next year, are required to take the multiple-shot regimen over many months. If they refuse they can be court-martialed.

For her part, Teresa thinks the vaccination holds the key to explaining her brother's sudden and mysterious death. She notes he received his first anthrax shot on April 13, and then another round on April 27, before being deployed on April 28. Soon Zeferino was battling a 102-degree fever, followed by stomach and spleen ailments, and then finally the deadly pneumonia.

This summer, there was an outbreak of more than 100 potentially life-threatening pneumonia cases among GIs, much like the illness Colunga suffered, and which some experts claim is related to the anthrax shots.

"It's like the soldiers are guinea pigs, and they don't really know if the vaccine works," says Teresa Colunga. "Our family has no answers to anything. They won't tell us the truth."

The Colunga family is not alone in asking tough questions. A small but growing chorus of voices, including Sen. Jeff Bingaman, D-N.M., Rep. Christopher Shays, R-Conn., and some veterans groups are raising concerns about the anthrax inoculation. United Press International has run a number of [stories](#) exploring the vaccine's possible dangers. Some health advocates insist the shots are putting soldiers' health needlessly at risk, and that the military does a halfhearted job of documenting adverse reactions and an even worse job of treating those servicemen and women affected.

The vaccine's American manufacturer strongly denies that his product is unsafe. "People are running around spreading misinformation about the vaccine -- it's kind of taken on a life of its own," says Tom Waytes, M.D., vice president of medical affairs for BioPort Corp., the country's lone manufacturer of the vaccine. He cites an exhaustive [2002 government-sponsored study](#) conducted by the Institute of Medicine, a branch of the National Academy of Sciences, which gave the vaccine high marks for safety. "There's no smoking gun. There is nothing evil about this vaccine," he says. "Yet people are still spreading myths about it."

The Institute of Medicine study, which reviewed all the available data, found that those who received the vaccine did not "face an increased risk of experiencing life-threatening or permanently disabling adverse events" immediately after getting the treatment. It also found that vaccine recipients were not at higher long-term risk -- although it noted that "data are limited in this regard (as they are for all vaccines.)"

But the study seems unlikely to quell the controversy. In February, on the eve of the war with Iraq, the president of the Australian Medical Association [announced](#) that in her opinion there was no definitive scientific evidence that the anthrax vaccine was safe. Weighing in after controversy

erupted when a number of Australian enlisted personnel refused to take the shots, she singled out the shortage of peer-reviewed scientific studies. And she challenged the chief of Australia's navy, who had reassured sailors that the vaccine was safe. "If they have that data, the medical profession in Australia would very much like to see it," she said.

Meanwhile, BioPort is currently fighting a tort liability lawsuit in Michigan, brought by over 50 military service members who are alleging injuries from the vaccine.

Critics also suggest that the administration's insistence that the vaccine be mandatory for troops is driven by politics. They point out that the Bush administration justified the war with Iraq on the premise that Saddam Hussein was sitting on a cache of biological weapons, as well as a mountain of anthrax. To the embarrassment of the White House, neither has been found, yet troops currently preparing for 2004 deployment to the region are all being forced to take the controversial shots. The not-so-subtle implication is that if the Bush administration were to discontinue the mandatory shots program, it would be admitting that one of the major reasons it used to sell the war was false.

"[Weapons inspector] David Kay can't find any anthrax in Iraq, and yet the military continues to court-martial service members for not taking the shots?" asks John Richardson, a retired lieutenant colonel in the U.S. Air Force Reserve and strident critic of the anthrax vaccine policy.

Even if the tragic death of Zeferino Colunga was caused by the anthrax vaccination, it could fall within the statistical reach of "reasonable safety" -- a tiny percentage of individuals will suffer acute, sometimes fatal reactions to any vaccine. But critics fear that adverse reactions, which often take unusual forms and can take years to be properly diagnosed, are only going to increase in the coming months as tens of thousands of soldiers return from the Gulf region, searching for answers to their mysterious health woes. In the first six months of this year, there have been 700 cases of adverse anthrax-vaccine reactions filed with the Food and Drug Administration.

That's why Sen. Bingaman introduced a Sense of the Senate [resolution](#) on Nov. 25 asking Secretary of Defense Donald Rumsfeld to review the vaccine program, reconsider punitive actions taken against soldiers who refuse it, and reevaluate the current threat of anthrax and smallpox attacks on U.S. troops. Bingaman noted that when anthrax letters were sent to Congress in 2001, Senate Majority Leader Bill Frist, R-Tenn., a medical doctor himself, advised Senate employees not to take the vaccine because of the "many side effects." And during the same anthrax scare, Rumsfeld conceded to reporters that he had not taken the vaccine. (Some argue that it's safer to take antibiotics after being exposed to anthrax than to be vaccinated in advance.)

Only a little over two years ago, the anthrax vaccine was under intense fire in Congress and the media. It was being administered to a relatively narrow group of soldiers, and was drawing sustained criticism from both Democrats and Republicans in Congress who questioned whether the vaccine was safe and wise. But today, with America at war, Bingaman and Rep. Shays are lonely voices -- even though the very same vaccine is now being given out to hundreds of thousands of troops, and the number of reported adverse cases has skyrocketed. The reason is simple: Congress is not about to challenge the military during wartime.

"They avoid the issue," says one Democratic congressional staffer. "It's kind of like when [President] Eisenhower talked about the dangers of the military-industrial complex -- this is the military medical complex thing that's going on, on the Hill. Plus, there's an unwillingness to question any military decisions right now. Republicans were running an ad [for President Bush] that basically said if you question the president's war on terrorism, you're un-American. People are afraid."

Bingaman's appeal in the Senate came on the heels of the Nov. 19 Pentagon announcement that it was "possible or probable" that vaccinations caused the death of Army reservist [Rachael Lacy](#), who died in April of pneumonia-like symptoms one month after receiving her anthrax shots.

"We need to reevaluate what we're doing in regards to the vaccine," says Rachael's father, Moses Lacy. "These young men and women understand the risk of the military and that they might have to go to Iraq, to go to war. But they did not understand the risks associated with the vaccines."

That charge is echoed by a soldier who claims that the day before he received his first anthrax shot in March, he and his fellow service members were briefed about the procedure by medics. "But they left out all the negative things about the vaccine," he says. "Instead of telling us a whole list of symptoms, they told us the side effects are very minimal and very rare -- maybe slight irritation of the skin."

The recently retired soldier, who requested anonymity, claims the anthrax shot has had a debilitating effect on him, causing sustained fatigue, dizziness, rashes, vomiting, memory loss and chills. "I can't work," he says. "I take steps like an old man; I can barely walk. You can draw a line through my life from the day of my anthrax vaccination and boom! There goes my health."

He also claims military doctors mocked him when he suggested his medical problems were connected to the vaccine, insisting instead it was an ear infection. "A lot of people don't want to hear about the anthrax vaccine, especially military doctors," says the soldier. "[Fellow soldiers] were asking me about my condition and I was honest, I told them I thought it was a reaction to the vaccine. That didn't go over well with my commanders, whose motto was '100 percent participation for the anthrax vaccine.' They told me to shut my mouth and not tell people it was the anthrax vaccine because it wasn't."

He was also scolded for trying to research issues surrounding the vaccine online. "They said, 'There's a lot of garbage on the Internet. You don't need to be looking up information.'"

Pentagon spokesman Turner insists, "Our policy is to report adverse reactions."

Other disturbing anecdotes abound. In 2001, Dr. John Buck became the first military physician court-martialed for refusing to take the anthrax shots. He told Salon that soon after he refused he had a meeting with an Air Force superior. Buck talked about how, in good conscience, he couldn't take the vaccine if he didn't believe in the quality of the science behind it. "At one point the commander said, 'Son, sometimes you have to check your integrity at the front door.' I about fell out of my chair," Buck recalls.

One sick Marine says military doctors told him point-blank he was suffering from a vaccine reaction, but refused to write it down as his diagnosis. "That's what I was there for, to get that diagnosis on paper. But they wouldn't. That left a real bitter taste in my mouth," says retired Marine Sgt. Will Hawkins. He reluctantly received a series of five anthrax shots in late '99 and early 2000. "I'm the type of person, if I'm taking Tylenol, I want to know how it's going to affect me. I found a lot of upsetting information about the anthrax vaccine and I said I didn't want to take it. I was told I'd be put up for court-martial if I refused. So I did take it."

Within days he was feeling severe joint pain. "It was hard to walk. It felt like I was crippling myself whenever I exercised. My body was just wearing down," says Hawkins, who was eventually discharged and has moved back to his home in Norman, Okla., where he grew up as a Boy Scout and Eagle Scout. In the wake of the vaccinations he suffered memory loss and a badly swollen liver that remained engorged for an entire year. He also spent a year and a half waging a bureaucratic battle in the hope of winning disability assistance for his condition. "It was an uphill

battle, fighting the military. I couldn't fight it anymore. It was taking a toll on me and making my symptoms worse." (He eventually won disability through the Veterans Affairs office.)

Today, the 30-year-old suffers debilitating migraine headaches three or four times a week. "The V.A. does job placement and tries to find you work. But I can't be employed and I'm not trainable because there's no guarantee I can work. There are days I can't get out of bed. There's just no way. It's something I have to deal with, trying to figure out what is the daily level of pain. I have my good days and bad days."

BioPort's Waytes flatly denies that anthrax vaccine has been shown to cause such severe chronic symptoms. "There are no cases of long-term disability caused by this vaccine," says Waytes. "Unfortunately, bad things happen to good people and they try to look for a cause: 'Why did this happen to me?' And a shot is a memorable event."

Since 1998, when the military decided to inoculate all of its active and reserve troops, the Department of Defense has given the anthrax vaccines to nearly a million troops. It claims that only one individual in 100,000 suffers severe adverse reactions. That means, according to Pentagon math, that only about 10 service members over the last five years have had severe adverse reactions to the anthrax vaccine.

But [Meryl Nass](#), a civilian physician in Maine and an expert on anthrax and biological weapons, scoffs at the Pentagon's estimate, in part because she's getting more than 10 calls every month from soldiers with likely severe adverse reactions to the vaccine. To date, she has treated nearly 2,000 patients, including former Marine Hawkins.

"I think at least 10 percent of recipients have continued problems afterwards. Other vaccines with continuing reactions are usually 1 in every 1,000," says Nass, who believes the military greatly underreports cases of adverse reactions. "I think everybody in the U.S. military knows somebody who is sick from the anthrax vaccine."

In the British military, which administers essentially the same anthrax vaccine, the shots are voluntary. (Only about half the soldiers take the shots.) According a report by the British National Gulf Veterans and Families' Association, they anticipate adverse reactions among 30 percent of the 22,000 troops who took the inoculation.

The anthrax program has been marked by controversy since its inception in 1998 when the Clinton-run Pentagon announced it would inoculate its 2.4 million service members, both active and reserve, as part of a multibillion-dollar biowarfare defense program. Officials insisted the shots were necessary to protect the U.S. military from the threat of anthrax, which had been developed for biological warfare.

"It would be unconscionable for us not to provide this kind of protection to our troops," says Turner at the Pentagon.

For a time, much of the controversy concerned whether the vaccine itself met acceptable manufacturing standards. For years, BioPort's facility in Lansing, Mich., struggled to win FDA approval, as inspectors found equipment being used without approval, labeling errors, and changes being made to the vaccine formula without proper consultation. In 1998 the FDA announced, "The manufacturing process for anthrax vaccine is not validated." The move effectively quarantined BioPort's vast supply of vaccine.

"They had just an horrendous track record at the facility in Michigan," says Russell Dingle, a retired lieutenant colonel with the Air National Guard in Connecticut who has researched the

vaccine for years. "If you go back and read the previous FDA reports, it's like the Three Stooges of vaccine production."

(Waytes at BioPort says the FDA's ruling on the facility was not surprising since the company had purchased it from the state of Michigan in 1998 and was in the process of a multi-year renovation.)

By 2000, with the release of a critical General Accounting Office report on the vaccination program, as well as the embarrassing admission that BioPort was simply unable to manufacture the vaccine in accordance with FDA requirements, the Pentagon was on the defensive. "We have been behind the ball," said Deputy Defense Secretary Rudy deLeon, testifying before Congress. Politicians on both sides of the aisle dressed down the military for misjudging the cost and popularity of the program as well as the availability of the vaccine.

As a 2000 presidential candidate, Republican Sen. John McCain, R-Ariz., called for a moratorium on the vaccination program. By the fall of 2000, then-candidate George Bush announced, "I don't feel the current administration's anthrax immunization program has taken into account the effect of this program on the soldiers in our military and their families. Under my administration, soldiers and their families will be taken into consideration."

By the summer of 2001, with the BioPort facility still not allowed to produce the vaccine and the Bush administration taking a close look at the whole process, "the program, for all intents and purposes, had ended," notes Dingle.

Also in 2001, Connecticut's attorney general, concerned the state might bear responsibility if its guardsmen got sick from the vaccine, wrote the Department of Defense and the FDA urging them to abandon the program. "In effect, the military is forcing its personnel to serve as human guinea pigs for an unlicensed drug that has not been proven to be safe or effective," wrote Richard Blumenthal. He also noted, "Since the vaccine has not been tested on humans, there is no basis for concluding that it is safe and effective."

The major concern about the vaccine's effectiveness is that it hasn't been tested against inhalational anthrax. When anthrax is used as a weapon it will likely be aerosolized and therefore inhaled. A 1994 report by the Senate Veterans Affairs Committee concluded that the vaccine "should be considered investigational when used as a protection against biological warfare."

Waytes insists, "Every bit of scientific evidence indicates [troops] would be protected" from inhalational anthrax.

Most of that second-guessing vanished with the still-unsolved release of the deadly post-Sept. 11 anthrax letters, which produced unprecedented fear about the mysterious killer. The letters set off a chain reaction, with the FDA quickly changing course and reapproving the BioPort facility, giving the company permission to produce massive amounts of vaccinations. This ultimately made it possible for the Pentagon to vaccinate mass numbers of troops.

"If the anthrax letters were never sent, then the FDA wouldn't have re-licensed the BioPort plant; then there would be no vaccination," notes Nass.

Still, as part of the 2002 deal, the FDA required the insert package for the vaccine to be revised; it now includes 40 possible serious adverse effects. BioPort also upped the percentage of recipients who suffer systemic reaction from just 0.2 percent to between 5 and 35 percent. That's different from the severe reaction rate, which the Pentagon insists is much, much lower.

Waytes explains that the percentage increase from 0.2 did not reflect a change in the vaccine itself, but rather improved monitoring techniques used in more recent studies. Rather than depending on people to call back to report reactions, newer studies kept much closer tabs on recipients, and therefore documented a potentially higher reaction rate.

"I had my fingers crossed that BioPort had improved its oversight and it wouldn't be as dangerous as it used to be," says Nass, one of the only doctors in America who treats anthrax vaccine victims. "During the [springtime portion of the] war I got no calls. But now the troops are coming back and they're sick and I'm getting calls, about one a day."

The surest way to avoid getting sick is not to take the shots. But soldiers who do -- and hundreds have -- face court-martial proceedings, which critics say are uncalled for.

"It would be like if you worked for Firestone when the exploding tire scandal broke and the management says to its employees, 'For benefit of the company, we want you to keep using the tires to demonstrate we have faith in Firestone.' That's what the military is asking soldiers to do," says Stephen Robinson, executive director of the National Gulf War Resource Center. "They're forced to take this absurd loyalty test and there's no safety net in the event you become ill."

In a 2000 court-martial case, Canada's top military judge ruled a soldier could refuse the anthrax vaccination, saying that the batch of vaccine was dangerous.

The U.S. Department of Defense, however, is taking a hard line. "If somebody disobeys a direct legal order they have to deal with the consequences," says Pentagon spokesman Turner. "We'd hope after people heard the facts, not the rumors, they'd take the vaccination."

But a steady stream of soldiers are refusing:

Ohio National Guardsman and Ohio State University journalism student [Kurt Hickman](#) faces 100 days of confinement, as well as getting kicked off the Guard, for refusing to take the anthrax vaccination. His trial is set for Dec. 13.

Pvt. Rhonda Hazley was court-martialed this summer for refusing. She feared it would injure the baby she was breast-feeding.

In July, 1st Lt. Erick Enz, a North Carolina-based helicopter pilot and Gulf War I veteran, refused the shots on religious grounds and pled guilty. He was dismissed from the service and ordered to serve seven months in prison.

Pvt. Kamila Iwanowska, a 26-year-old reservist and recently naturalized Polish immigrant, was court-martialed for refusing to receive the anthrax vaccine on the grounds that it might hurt her chances of getting pregnant.

In June, Navy sailor Tony Goodwin was sentenced to 40 days in the brig, demoted and had his pay docked for refusing his shots.

"When you start to dig a hole and find yourself in it, the first thing you should do is stop digging," says Buck, who was court-martialed in 2001 and now works in an emergency room at a Houston hospital. "I can't tell you how much I wish [the Pentagon] would stop digging. But I don't think they will. What I think will happen is a new vaccine will be created and they'll switch over, and the problems associated with this vaccine will not be disclosed for 10 or 15 years until all the major players have moved on. And years from now we'll watch about it on the History Channel, alongside programs about the Gulf War syndrome."

Looking back, former Marine Hawkins says, "Yes, I wish I had refused the vaccine. But if you asked me if I'd serve my country I would, no questions asked."

Hawkins knows his health, his ability to function day-to-day, will never be same. "I have to deal with the consequences for the rest of my life," he says. "But I've been trained as a Marine to survive, so that's what I'm going to do."