Capt. Jason Nietupski, a U.S. army reservist, initially thought nothing of it when the military ordered him to get a vaccine against anthrax.

Mr. Nietupski received the shot -- a standard army precaution against enemy biological attacks -- before his deployment to Korea last year. But soon after his first inoculation in February, the 29-year-old Mr. Nietupski showed up at an urgent-care facility with sores all over his mouth and throat. "The side of my tongue was all raw with little canker sores, and bloody mucus was coming out of my nose," Mr. Nietupski says.

His maladies, ultimately diagnosed as an autoimmune disorder in which his body accidentally attacked itself, grew worse as he got the next two installments of the six-shot regime. Mr. Nietupski, and several of the doctors who have examined him, believe the anthrax vaccine caused his severe reaction, and may also be to blame for the blood clots Mr. Nietupski experienced in his legs months later. The clotting problem is so serious that he can no longer jog, or even stand for very long.

Mr. Nietupski's case, and hundreds of others in which soldiers claim harm or disability from the shots, has put the U.S. military in a difficult position. It curbed the anthrax vaccination program in the wake of quality-control problems and complaints about side effects. Yet the armed forces are now in the midst of a massive mobilization in which troops are likely to confront terrorists, the kind of people widely viewed as most likely to use biological weapons.

Returning to wider inoculations risks sparking major protests, and even resistance. To date, 102 people have been court-martialed for refusing to take the vaccine, according to the Department of Defense. Hundreds of others have resigned to avoid taking the vaccine, according to critics of the military's program.

Since 1998, only about 521,000 people have gotten some or all of the shots, which must be given six times over an 18-month schedule. Over the past year, vaccination has continued at a minimum level, with only high-risk personnel -- such as those going overseas -- getting the shots. There are about 2.4 million people serving in the military and its reserves.

"The manufacturer has been unable to pass a single inspection," says Capt. Dale Saran, a U.S. military lawyer who defended two of those court-martialed for refusing to take the vaccine, which was licensed by the U.S. Food and Drug Administration in 1970 and is now made by BioPort Corp., of Lansing, Mich. "No vaccine today would be made with these procedures."
BioPort concedes that the FDA has found deficiencies every time it inspected the plant since it bought it in 1998. But it says it has either corrected them or is in the process of doing so. The U.S. Army acknowledges that more than 30% of those getting the vaccine have experienced minor side effects, but they say serious problems are highly unusual.

Anthrax, normally a scourge of livestock, is rare in humans. But it is viewed by the government as one of the top seven most likely biological weapons, along with smallpox and pneumonic plague. The reason is that it is fairly easy to obtain, from the soil or from infected animals, and very deadly. Without prompt treatment, the disease kills an estimated 90% of those exposed.

Before Sept. 11, the future of the anthrax vaccination program looked uncertain. The effort, begun by the Clinton administration in 1998 after intelligence found Iraq and other enemies might be developing anthrax-based weapons, ran into problems nearly as soon as it started. That same year, after the FDA found myriad problems with the plant's sterility and quality, BioPort shut it down for renovations. And, even though there were enough doses already made to continue vaccination, skeptical military employees began digging in their heels. BioPort says it has made some vaccine since 1998, but that it won't be released for use until the FDA clears the plant.

President Bush, during his election campaign, told U.S. Medicine, a trade publication focusing on federal health policies, that the anthrax vaccination effort "has raised numerous health concerns and caused fear among the individuals whose lives it touches." He added, "Under my administration, soldiers and their families will be taken into consideration." A Defense Department memo dated Aug. 10 outlined plans to "review and assess" the performance of BioPort, and to develop long-range plans to replace it with a "dedicated vaccine facility to serve the national interest."

But today, flaws and all, closely held BioPort has become a key national-security asset. Three employees of tabloid publisher American Media Inc. have been exposed to anthrax in Florida, in what investigators suspect was a criminal act. The Department of Health and Human Services, after a long silence on the matter, has said in recent days that the FDA is working closely with BioPort and hopes to be able to reopen the facility within six weeks -- rather than in the three or four months expected earlier.

The government's statements "are a clear indication that they plan to cut corners to make this happen," says Col. John Richardson, a Chapel Hill, N.C., pilot who retired from the U.S. Air Force last year in part due to concerns about the military's mandatory vaccine policy.

Vaccination against anthrax is critical because it is difficult to detect an attack early enough to save the victims. One of the three America Media employees who were exposed to the disease died despite doses of antibiotics. Due to potential side effects, and the inconvenience of repeated shots, it's unlikely that a preventive anthrax vaccine would be given to the public. However, many experts believe that such a vaccine would be useful after an exposure, because animal studies have shown anthrax can survive in a dormant form for at least a month even with heavy antibiotic therapy.

Since 1970, the sole U.S. supplier of anthrax vaccine has been a laboratory
in Lansing formerly owned by the state of Michigan. The state decided in the mid-1990s to put the facility up for sale, but there was scant interest from major pharmaceutical firms. In early 1997, the FDA issued a notice that it planned to revoke the lab's license after a failed inspection.

Enter Fuad El-Hibri. Mr. El-Hibri had previously been a director of a British maker of bio-defense vaccines for anthrax and botulinum. Sensing an opportunity, Mr. El-Hibri, a German national of Lebanese extraction, formed BioPort to bid for the lab. He also brought in on the deal a powerful ally, retired Adm. William J. Crowe Jr., a former chairman of the joint chiefs of staff who also served as U.S. ambassador to Britain under President Clinton. Mr. El-Hibri is now a U.S. citizen.

Mr. El-Hibri later testified before a U.S. House committee that other stakes in the company were owned by his wife Nancy and by a Netherlands Antilles company controlled by his father, Ibrahim El-Hibri. BioPort won the auction for the Michigan lab with a bid of about $24.8 million, and closed the deal in September 1998. Less than two weeks later, Bioport was awarded a $45 million, sole-source contract to supply anthrax vaccine to the Pentagon.

Adm. Crowe's involvement later raised eyebrows in Congress. The admiral clearly had high-level contacts in the Pentagon, and had been one of the few prominent former military leaders backing Mr. Clinton's election bid in 1992. In addition, congressional staffers familiar with the situation say Adm. Crowe paid only a token amount for his 22.5% original stake in a holding company that controls BioPort by owning just over half of its shares.

Adm. Crowe "was used as the man in the window" by BioPort, says Lawrence Halloran, staff director of the subcommittee on national security of the House Committee on Government Reform, which held numerous hearings on the anthrax vaccine. "He paid virtually nothing for his stake, and they got the use of his good name."

In an interview, Adm. Crowe said he had gotten to know Fuad El-Hibri after a long association with his father, and had agreed to join the company's board "because it seemed to me like a pretty good idea" to be associated with something that might help the U.S. defend against "an offensive weapon."

Adm. Crowe said he was unprepared for the "storm" of controversy his role in the company has generated, but stated "I haven't attempted to influence" the BioPort contract "in any way." The admiral also said his position as a director of the company is unpaid, adding that BioPort's financial woes have meant that "until now, not a single cent" has come from his stake in the company.

Jay Coupe, a longtime aide to Adm. Crowe who acts as his spokesman, said the admiral "didn't pay anything" for his stake in BioPort, which he said was the equivalent of about 12% or 13% of the company. "As is the case with a lot of former government officials, one of the incentives to bring him on board was a piece of the action. Unfortunately, the action has been nonexistent."

Mr. Coupe said the admiral strongly believes the anthrax vaccine program is right for the troops he used to command, and has taken the six-shot course himself.
Mr. Halloran says the Defense Department, when it focused on bioterror after the Gulf War, could have taken the time to develop a new vaccine that only had to be given once or at most three times, with predictable characteristics. Instead, he says, "they took the easy way out" and selected the vaccine which was originally developed in the 1950s and reformulated in the 1960s. "Now we're stuck with this thing."

In 1998, shortly after taking over the plant, BioPort decided its problems were so grave that it needed to be shut for a major overhaul. In August 1999, the government gave the company an additional $24.1 million in "extraordinary contractual relief," according to a Defense Department report, and restructured the original deal so that the company would be paid between two and five times more per dose, for a smaller number of doses.

But even after the financial boost and extensive renovations, Bioport's plant was found wanting in a November 1999 inspection, and again in October of last year. In a report dated Oct. 26, the FDA lists three pages of reasons why a section of the plant where vials are filled with the anthrax vaccine and other products does "not assure sterility." Specifically, inspectors found rust on equipment, including an oven in the plant, and saw smoke seeping into an area where it should not be. Also, the FDA report said, "employees routinely exit and enter" through a curtain into a room where product is located and "do not always sanitize their hands" after touching the curtain. The curtain, the report says, was "discolored," possibly from rust.

Andrew J. Bacevich, director of the Center for International Relations at Boston University, who has studied the anthrax-vaccine program, says it has been "massively mismanaged" by BioPort and by the Pentagon. BioPort has a "horrible track record in terms of its performance" and yet the Department of Defense "seems to think the answer is to give them more time and more money."

Tom Waytis, vice president of medical affairs at BioPort, acknowledges that the plant has had some sterility problems -- for example, at one point, tests of empty vials found bacteria. However, all product made in the plant at that time have been put aside in a location he won't disclose. "There never has been a contaminated product released," he said. The company is planning to submit its final application to the FDA for plant certification by Monday.

Lt. Col. John Grabenstein, an army epidemiologist who tracks reactions to the vaccine, says negative side effects are "minimal" given that some 2.1 million doses have been given to 521,000 people since 1998. Some 1,628 of those people have reported problems after getting the vaccine, mainly redness or swelling at the site of the injection. Ten had such massive swelling in their arms after the vaccine that they needed to be hospitalized, a reaction which Dr. Grabenstein acknowledges was probably caused by the vaccine. An additional 15 were successfully treated for anaphylaxis, a potentially fatal allergic reaction, which can cause lungs to spasm and the throat to swell up.

But critics of the vaccine, mostly current or former military personnel, say the official side-effect numbers are artificially low because the military discourages reporting them. Mr. Nietupski says that, although he was
examined by more than a dozen military doctors since his symptoms began in February of last year, none of them initially reported them to the FDA. Only in March, a year later, after Mr. Nietupski complained to members of Congress, was his case reported.

The Department of Defense says it encourages reports of vaccine side effects by doctors, and that patients may even submit the reports themselves if they like.

Six people have died within a short time after getting the vaccine, according to reports made to the FDA. Three died of some sort of cardiovascular problem, one committed suicide, one had cancer and another, Sgt. Sandra L. Larson, died in June of last year of a rare blood disorder. Dr. Grabenstein says a panel of civilian experts have looked at the deaths and found no evidence they were caused by the vaccine. "People are saying 'I'm sick and I've been vaccinated.' I'm sorry that you're sick, but A following B doesn't mean A caused B," he says. "It's far more intricate than that."

Dr. Grabenstein says that the disorder experienced by Mr. Nietupski, called Stevens-Johnson Syndrome, could possibly have been caused by the anthrax vaccine, given that it has been linked to some other types of vaccines. However, he says, the blood clots are very unlikely to have been caused by the vaccine. He says the civilian expert panel, called the Anthrax Vaccine Expert Committee, hasn't ruled on Mr. Nietupski's case yet.

Meryl Nass, an internist in Freeport, Maine, who has treated several military personnel who have developed chronic fatigue and other ailments, says she believes Sgt. Larson's death and at least one of the others she is familiar with could have been caused by the vaccine, through a sort of "autoimmune reaction," in which the body's defenses go on overdrive after getting the vaccine and accidentally destroy its own tissues.

Sgt. Larson, 32 years old, started to feel sick after getting her final anthrax shot in March of last year. She noticed rashes on her arms and legs and felt constantly tired. In April, after she began to hemorrhage, she was admitted to the intensive care unit at Kansas City Medical Center, and diagnosed with aplastic anemia, or a severe lack of blood cells. In the hospital, convinced her malady was caused by the anthrax vaccine, Sgt. Larson began to do some of her own research. Two months later, on June 14, she died.

Dr. Nass, who reviewed Sgt. Larson's case after her death, believes her malady could have been caused by the vaccine, as a result of an autoimmune reaction in which the body attacks its own blood cells. In another case, BioPort employee Richard Dunn, who received the vaccine to protect him against possible exposure to anthrax on the job, was found to have died from a heart attack after "polyarteritis nodosa," an autoimmune disease in which the body mistakenly attacks its own arteries.

Medically, there's no way to tell whether any individual problem was caused by the vaccine. The only reliable method is to look at large groups to see whether particular maladies are more common in those who have been vaccinated than in the general population. Dr. Grabenstein says 18 studies have found no higher incidences of serious maladies, such as blood clots or autoimmune disorders, among those getting vaccines.
But few of those studies, which include many by military scientists and some work dating back to the 1960s, have been "peer reviewed," or examined by experts prior to publication. In a 1999 report, the Institute of Medicine found "insufficient evidence" to determine whether the anthrax vaccine is safe or not. The IOM is now preparing another report on the matter, and Dr. Grabenstein says the military is "pleased" with where it appears to be headed. The IOM couldn't immediately be reached for comment.

Sgt. Larson's sister, Nancy Rugo, of Spokane, Wash., is now continuing her search for answers. Before Sgt. Larson died, she told her sister "be sure you finish this search for me, because I know it's the vaccine," Ms. Rugo says. Ms. Rugo, following through on her sisters' wishes, is comparing notes with others' whose family members have died or suffered serious disability after getting the shots. "As far as I'm concerned," says Ms. Rugo, "this is an unsolved mystery."

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