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## Mutiny of the Guinea Pigs

### **The public may have a new urge for anthrax vaccinations, but some militaryvets contend their injections ruined their lives**

*By Matt Fleischer-Black, The American Lawyer*

Inhaled anthrax causes a rapid demise. Fever and lethargy come first, followed by headaches and coughing. Breathing becomes difficult. Then shock begins, and death is almost inevitable. The fever and queasiness that struck U.S. Army specialist Sandra Larson wasn't caused by anthrax.

Her trouble began in March 2000, shortly after a shot of the vaccine to prevent such infection. She grew sluggish, developed rashes and began to suffer heavy vaginal bleeding. Soon after, the doctors determined that her body had ceased to create bloodcells, a condition called aplastic anemia. She fell into a coma, and, 12 weeks after the shot, she died. The Pentagon says that Larson's death -- and other apparently vaccine-related ailments -- were caused by something unrelated to the vaccine, and that such suggestions have been spurred by soldiers spending too much time surfing the Web.

In 1998, the Department of Defense mandated that all soldiers take a set of six injections. According to the Pentagon, only 10 of the 526,000 soldiers who have had the shots have reacted badly to the vaccine. Military doctors didn't attribute Larson's death to the vaccine, saying that the anemia was idiopathic -- that is, without a known cause.

The public may have clamored for anthrax vaccine in the wake of the terrorist mailings last autumn, but some veterans believe that the vaccine destroyed their lives. Some veterans and current members of the armed services, along with a handful of sympathetic members of the U.S. Congress, have heatedly questioned the manner in which the vaccine was manufactured, and the reason that the Department of Defense continued immunizing the armed forces after major safety violations had been discovered at the vaccine factory.

A federal lawsuit filed by Sandra Larson's sister, Nancy Rugo, and 14 ailing veterans could focus new scrutiny on the Pentagon. The plaintiffs have accused the Pentagon's sole provider of the vaccine, the BioPort Corp., of making an adulterated and dangerous product.

Even uglier, the veterans assert, BioPort tested a novel and unapproved use of its drug on them, knowing that the soldiers could not refuse the shots.

"When young men and women volunteer to serve in the armed forces, they don't lose the right to an essential human dignity," says the veterans' lawyer, Alan Milstein. "They still deserve what every citizen is entitled to when it comes to medical care -- the opportunity to make an informed decision about whether or

not to take that drug." The veterans' ailments may attract sympathizers, but their suit faces a multitude of hurdles in court.

To start, long-standing case law pretty much tells disabled veterans -- in the jargon of the drill sergeant -- to suck it up. A soldier cannot sue the military over injuries sustained on active duty, and contractors enjoy similar protection under the so-called contractor defense.

BioPort, working under Department of Defense contracts, has a ready excuse in that it, like an inoculated soldier, was just following generals' orders. (Executives at the Lansing, Mich., company declined to speak on the topic of BioPort's relationships with government agencies, although they did discuss safety issues.) While the contractor defense may be invoked, the BioPort-Pentagon relationship at the center of the case has quirks that differentiate it from previous cases.

Judge Colleen Kollar-Kotelly of the U.S. District Court for the District of Columbia faces several rounds of defense arguments that will require arcane legal analysis and intensive factual review. And the more digging she ends up doing, the more risk the Pentagon faces. The Department of Defense could lose a lot of taxpayer money; the Pentagon has agreed contractually to absorb the cost of wrongful injury and death judgments against the anthrax vaccine maker.

The federal government only rarely indemnifies private businesses, like those supplying Space Shuttle parts, air traffic control computers, nuclear facilities and the swine flu vaccine. That flawed 1970s medicine cost the government \$92.9 million in payouts to injured vaccine recipients. This case could subject the Pentagon to political embarrassment as well as a big payout.

The vaccine case will shine a spotlight on the Defense Department's assistance to a company that other government agencies repeatedly found to be in violation of safety regulations. If BioPort's lawyers argue a government contractor defense, Kollar-Kotelly will have to review what the Pentagon knew about BioPort, and when the agency knew it. Given that Connecticut Republican Rep. Christopher Shays has accused the Pentagon of giving different answers to key questions, depending on who has asked those questions, the judge may want to grill Defense officials.

Among the possible questions: Did the brass know that BioPort had failed to tell the Food and Drug Administration of production changes that might have compromised safety?

The government's indemnification gives Department of Justice attorneys the right to step in and defend the case themselves. But the financial and political stakes riding on the case have put the government's lawyers in a strategic bind. They can try to protect the Pentagon's supplier by acknowledging that the agency authorized everything that BioPort did (a fact at least suggested by congressional investigations).

To confess that level of involvement, however, Justice risks giving new fuel to the grassroots campaign being waged against the mandatory vaccination policy. To deny that Washington knew what was going on will leave BioPort -- and millions of dollars -- vulnerable. "I suspect that the guys over at the Department of Justice have a real tough issue here," says Barry Steinberg, former chief of the Army's litigation division and now a Washington, D.C., partner at Kutak Rock.

The ideal for Justice would be to get rid of the case early. Otherwise, the president and the secretary of Defense might have to watch a jury decide that Americans don't have a viable vaccine to fight biological warfare.

The veterans' vaccine case is right up Alan Milstein's alley. The 47-year-old partner at Pennsauken, N.J.'s Sherman, Silverstein, Kohl, Rose & Podolsky first garnered notoriety after he successfully sued the University of Pennsylvania on behalf of the father of Jesse Gelsinger, a healthy teen-ager with a genetic disorder, who died in 1999 after volunteering for gene therapy experiment. Milstein successfully settled that case after a month, without deposing a single witness.

This splash was all it took for top medical and law schools to invite him to speak. Milstein has since filed several lawsuits on behalf of self-declared guinea pigs injured during medical experiments, mostly at universities. The people at Penn weren't much impressed by the longtime antagonist of insurance companies and the attention he's attracted.

"There's plenty of lawyers who know what they're talking about, and they don't [have] this sort of ambulance-chasing ethic," says Glenn McGee, a bioethicist at Penn. "As a social policy, he's a disaster." Reading Milstein's Penn complaint, though, persuaded Nancy Rugo, Sandra Larson's sister and a name plaintiff, to hire him.

Other attorneys she contacted had told her that the government contractor defense was too big an obstacle. Not Milstein, who admits that he's a self-promoter; members of his own household, he says, have questioned his motives before. Milstein insists that he's got a real case, maintaining that he can pry BioPort from behind the legal shield afforded all military business.

He intends to use reports by the FDA that BioPort's factory lacked fixed operating procedures or basic quality controls. "The defense does not hold if they perform the contract in a manner that is contrary to the standard of care in the industry," he says.

First, though, Milstein will have to be creative enough to keep the case in federal court. The Michigan Department of Public Health held the vaccine's license until 1995, when a temporary state agency, the Michigan Biological Products Institute (MBPI), was created, with an explicit time table for the institute's eventual privatization.

BioPort didn't come into existence until June 1998, four months after the Defense Department began universal mandatory inoculations with the vaccine. All of the vaccine given to soldiers has come from stockpiles made from 1991 to 1998 by MBPI or its predecessor.

BioPort won't comment, but it surely will argue that the vaccine was all made by the state government, which would give the company grandfathered protection under the doctrine of sovereign immunity. Milstein has sued the state agencies, too, arguing that their vaccine sales constituted a direct commercial, rather than governmental, activity. "They were not doing anything for Michigan residents," he says. The deciding factor in previous cases generally has been whether the state treasury would have to pay, says Evan Caminker, a professor at the University of Michigan.

No judge appears to have addressed an instance where a state agency wouldn't pay because it has been indemnified by the federal government. If BioPort loses the sovereignty argument, its government contractor defense would seem to offer it an easy way to close the case down. The Pentagon has invested nearly \$150 million in BioPort; has been the vaccine maker's main customer; has helped supervise the testing of the vaccine; and has performed most of the major studies on the vaccine.

E-mails unearthed by congressional investigators indicate that, in certain months, the Defense Department or its consultants were at BioPort's facility every day. As Brig. Gen. Eddie Cain wrote in a May 1999 e-mail about attacks by Rep. Shays, the agency's chief congressional critic: "Wait until he finds out that DOD is calling all the shots on sight [sic]." (A Defense Department spokesman has said that the brigadier general's comment makes no sense, as the Pentagon didn't have people at BioPort until several months later.)

To sustain a government contractor defense in court, and to force Milstein into the hopeless situation of suing the military directly, BioPort must convince Judge Kollar-Kotelly that its relationship with Defense meets a three-part standard established by the U.S. Supreme Court's 1987 ruling in *Boyle v. United Technologies Corp.* The first of these standards is that the contractor must be following detailed specifications set by the government.

The Michigan health department's 1993 contract, which appears to cover the manufacture of the doses that soldiers received, stipulates mainly that the delivered product will conform to the FDA license and to all applicable regulations.

Those standards would not be detailed enough for the contractor defense, says Mark Dombroff, the attorney who won the Boyle case. (Still, the judge can review the facts and come to her own conclusions about Defense and BioPort's interdependence.) If Milstein doesn't eliminate BioPort's government contractor defense any other way, Dombroff says, the question of compliance is likely to do in the company anyway.

In May 1993, May 1994, May 1995 and December 1996, the government cited the factory for production problems.

In February 1998, investigators spotted 49 pages of objectionable practices, including Bioport's failure to maintain specified operating procedures. A violation such as that generally would foreclose the defense.

An anthrax vaccine was first developed in the 1950s; the Michigan health department version was licensed in 1970 as safe and effective in preventing skin-borne anthrax.

By 1985, the army's medical researchers expressed concern that it was proving "highly reactogenic," and solicited proposals for an improved version. None was developed. Twelve years later, in December 1997, the secretary of Defense announced that the department would inoculate the entire armed forces against the looming bioterror weapon.

The Department of Defense says that 18 different studies have demonstrated the safety of the vaccine, and BioPort maintains that its product has been certified as

safe for 30 years. "Over the last three years, there's been even a ton more data on safety done. This is probably the most highly scrutinized vaccine of recent times," says Tom Waytes, Bioport's vice president of medical affairs.

The vaccine's safety has been affirmed by the Centers for Disease Control and Prevention and by the World Health Organization. An anthrax vaccine victims' network says that 2,000 veterans, out of a half-million inoculated, have attributed their health problems to the vaccine. Yet, even if all of those problems were legitimately tied to the vaccine, the Pentagon says, that still would reflect a standard rate of trouble for vaccines. As it did for all soldiers, Defense handed Sandra Larson a version of the manufacturer's product warning insert, which said that the vaccine's chief side effects were typically a small area of localized swelling near the site of the shot and flu symptoms that would go away within a few days.

Even if the vaccine was in theory only a mild risk, Milstein says, BioPort's sloppy factory, its withholding of important information from regulators and its failures to conduct basic quality control tests magnified the risk to dangerous levels. The strongest part of Milstein's case against BioPort is that its factory was an awful mess. The FDA repeatedly found consistency problems at the Michigan factory that could have left some doses contaminated. Inspectors at the facility found no regular check of the production line's sterility, according to a March 1997 FDA letter to the company.

Nor did they find (take a deep breath) cleaning schedules, regular quality-control checks of components or the finished vaccine, separate areas to prevent improper mixing of components or procedures to prevent microbial contamination. Yet the vaccine production continued for another 11 months. In February 1998 an FDA team found that expired lots of the vaccine had been redated after expiration, and that the vaccine lots that had provided the doses for Sandra Larson may have been contaminated or otherwise unsafe.

Some had been tested for potency, but not for stability nor for contamination. The company shutdown the production line (and still hasn't reopened it). The next month, inoculations began at bases throughout the military.

The plaintiffs say that BioPort violated its duty to ensure that they were fully warned of the vaccine's dangers. On Oct. 26, 2000, the FDA warned the company that it needed to report adverse reactions, specifically citing Sandra Larson's case.

Then, on Oct. 23, 2001, a week after Milstein filed the lawsuit, the Government Accounting Office (GAO) revealed that BioPort's warning insert claimed a lower incidence of systemic reactions than had been revealed in studies of the previous decade. "It's a total disgrace, the way which BioPort has not gone through the normal channels," says Milstein.

Replies Bioport's Waytes: "We are working to update the product insert as all manufacturers do on a regular basis.

That's an issue that takes meetings and negotiations with the FDA." Top military doctors had seen enough adverse reactions from the vaccine two years ago that the Walter Reed Army Medical Center changed the diagnostic algorithm for determining trouble after anthrax immunizations. Since then, doctors there have

watched for anaphylaxis, systemic allergic reactions, rashes and other conditions.

According to a transcript from a May 1999 Defense meeting on the vaccine, Dr. Renata Engler said that serious reactions to the vaccine were "fortunately still a rare event, thank God, but you like to be able to not feel in retrospect: 'Gee, I pushed this immunization and maybe I shouldn't have.'

" That private doubt may not settle any questions about whether BioPort's ineptness caused Sandra Larson's death and the other plaintiffs' injuries. But when the doctor is called to testify, she will remind the Justice Department lawyers overseeing the trial that accusations of another, more emotionally unnerving level of negligence are still hanging in the air: that in the military's can-do determination to get all of its soldiers vaccinated, it failed to do everything it could to protect those soldiers' health.