



The Anthrax Dilemma

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In December 1997 the Pentagon announced that all 2.4 million active duty military personnel and reservists would be inoculated with a vaccine against anthrax, a potential biological weapon. This program is questionable because of unknown efficacy of the vaccine, unknown risks to those who will be inoculated; coercion in the inoculation effort; and other ethical and policy reasons. New strains of anthrax may have been developed specifically to defeat the current vaccine. Previous immunization programs conducted by the Pentagon have been open to criticism. Researchers unaffiliated with the Pentagon should conduct further studies on the vaccine, and civilian public health agencies, including the Centers for Disease Control and Prevention and the National Institutes of Health should participate in design, testing, implementation, and oversight. A more effective way to deal with the threat of biological weapons is for the US to dismantle its nuclear capability, thereby removing an important incentive for other countries to develop alternative weapons of mass destruction. [M&GS 1998;5:97-104]

In October 1996 the *Washington Post* carried a front-page story about a plan being formulated by US military leaders to inoculate all members of the US armed forces with anthrax vaccine. The plan was developed, it was reported, because of the perceived risk of attack on US troops by weapons containing anthrax spores. In December 1997, despite public controversy about the inoculation program, the Pentagon announced that all 2.4 million active duty military personnel and reservists would be inoculated [1]. One of the first to be publicly inoculated was the Secretary of Defense, William Cohen.

Anthrax is a highly virulent disease of animals, especially ruminants, caused by *Bacillus anthracis*. When transmitted to humans, usually by contact with infected animals or their products, the disease can take one of three forms. Cutaneous anthrax, which has in the past been quite common among certain occupational groups such as farmers, wool-handlers and tanners, causes severe skin ulcerations and may be accompa-

nied by myalgia, fever and vomiting. It is treatable by penicillin and other commonly-available antibiotics and is virtually never

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The Anthrax Vaccine Immunization Program: The Military View

[Editor's note: Secretary of Defense William Cohen announced in May 1998 that the entire US military force, active and reserve, would be vaccinated against anthrax. The program is to be implemented in four stages. Vaccinations have already begun for units deployed in "high threat areas" of Southwest Asia and Korea and will continue through fiscal year 2000. Vaccination of all remaining forces will begin in fiscal year 2003. As of August 1998 more than 48,000 military personnel in the first series had received initial vaccinations. On August 14, at a press briefing on the decision, Dr. Sue Bailey, the Assistant Secretary of Defense for Health Affairs, and Rear Admiral Michael L. Cowan, Deputy Director for Medical Readiness for the Joint Staff, presented the Pentagon's view that the \$130 million vaccination program is safe and effective. Following are extracts of the core arguments and responses to key criticisms presented at that briefing. The full text, which could not be reprinted here for reasons of space, can be found at the Total Force Protection Website at www.defenselink.mil/other_info/protection.html]

Dr. Bailey: All of...Secretary [Cohen]'s conditions [for approving the anthrax vaccination program] have been met.

First, the Joint Program Office for Biological Defense contracted with Mitretek Systems, Inc., to perform independent supplemental evaluation of testing being conducted by the manufacturer on all lots of anthrax vaccine, previously approved by the FDA...Initial lots have passed testing and will provide sufficient dosages to support the execution of the first part of the plan.

Second, each Service has implemented a tracking system that will fully document anthrax vaccinations and transmit the required data to the...Defense Enrollment Eligibility Reporting System....

Third, each Service developed implementation plans that specify how they will administer the vaccination program for the total force....

Fourth, Dr. Gerard N. Burrow, Special Advisor for Health Affairs for the President of Yale University, conducted an independent review of the health and medical aspects of the department's anthrax vaccine immunization program. Dr. Burrow completed reporting on his review on the safety and efficacy in February of '98. A copy of Dr. Burrow's report can be obtained from the DOD web site [http://www.defenselink.mil/other_info/protection.html]....

...The vaccine has been shown to be safe and effective. It has a 28-year history and is FDA licensed since 1970....[I]t has been given to veterinarians and we have also been giving it to special forces so that we now have a long history of safe use. We have given over 133,000 doses and we've only had seven adverse effects.

Q: Are you concerned that other biological agents will pose more of a threat now that potential enemies will know that all US service members will be inoculated against anthrax? What kind of other agents are you looking at?

Admiral Cowan: Our over-arching policy is that if we have a rec-

(continued on page 100)

fatal if treated. Gastrointestinal anthrax is caused by ingestion of contaminated meat. It is now quite rare, but sporadic outbreaks have occurred in areas where the disease is endemic. Human infection occurs when a break in the pharyngeal or intestinal mucosa permits invasion of the intestinal wall; hemorrhagic necrosis and septicemia with a high mortality rate may follow.

Inhalation anthrax, due to inhalation of anthrax spores, causes infection of the mediastinal lymph nodes with spread to the adjacent mediastinal structures. Pulmonary edema and pleural effusion with severe respiratory distress may develop, followed by cyanosis, shock, and coma. Even with intensive treatment, the outcome is usually fatal. Aerosol inhalation appears to be the pathway for human exposure preferred by those planning to use anthrax as a biologic weapon.

Anthrax has long been considered a potential biologic weapon because anthrax spores remain infectious under a wide range of adverse conditions. The Japanese biologic warfare effort in Manchuria in the 1930s, the infamous Unit 731, developed weapons containing anthrax spores [2]. The United States and Britain stockpiled anthrax spores for use as biologic weapons during World War II and tested them on Gruinard Island off the coast of Scotland. The island remained off-limits to humans for 45 years after the test and remained so until formaldehyde treatment was used to decontaminate the soil. An anthrax epizootic in Zimbabwe in the late 1970s may have been caused by deliberate spread [3]. Anthrax spores are believed to have been stockpiled by Iraq and perhaps by other nations as well, although it is not clear whether these organisms were weaponized.

The vaccine that the Pentagon is using is produced by one supplier, the Michigan Biologic Products Institute (MBPI) operated by Michigan's Department of Health under contract to the Department of Defense. The vaccine was first developed during the 1950s, was reformulated in the 1960s, and was approved by the US Food and Drug Administration (FDA) for general use in 1970. It has been given to about 3,000 veterinarians, people who work with livestock or animal products, special ops troops, those involved with vaccine manufacture, and anthrax researchers. The vaccine regimen recommended for military personnel includes a series of six inoculations. The first three are given two weeks apart, followed by inoculations at six months, 12 months, and 18 months. A yearly booster inoculation is also recommended.

This program appears to many observers to be questionable because of the

unknown efficacy of the vaccine for the purpose for which it is being used, the unknown risks of the vaccine to the personnel who will be inoculated, the coercion being used in the inoculation effort, and a number of other ethical and policy reasons.

Efficacy

There is no good reason to believe that the MBPI vaccine will be effective in protecting troops against airborne infection with anthrax, the pathway that would most likely be used by biologic weapons. The only published human efficacy trial of an earlier anthrax vaccine was a study in the late 1950s and early 1960s in a mill that processed raw imported goat hair contaminated with *Bacillus anthracis* and in which clinical anthrax infections occurred [4]. Some protective value against cutaneous anthrax was noted, but there was an insufficient number of cases of inhalation anthrax to reach any conclusions about the efficacy of the vaccine in the prevention of inhalation anthrax.

A controlled trial that involved purposeful exposure of humans to inhalation anthrax would obviously be unethical, but experiments have been done exposing monkeys and guinea pigs to inhalation anthrax [5,6]. These trials of the vaccine have yielded contradictory results. However, the only two Fort Detrick studies that studied vaccine efficacy against multiple anthrax strains isolated from around the world yielded similar results [7,8]. In the first study, 9 of 27 strains tested killed at least 50% of the vaccinated guinea pigs. In the second, 26 of 33 strains tested killed at least half the guinea pigs. When the Senate Veterans Affairs Committee examined the issue of efficacy and safety of the vaccine in 1995, it recommended that "the vaccine should be considered investigational when used as a protection against biologic warfare."

Further complicating the question of efficacy is the consideration that new strains of anthrax may have been developed specifically to defeat the current vaccine. It has been clear for some time that recombinant DNA technology may be used to alter agents that cause illness so that they are no longer as susceptible to vaccines or to antibiotics. Researchers in Russia disclosed in the British journal *Vaccine* in 1997 that they had genetically engineered a strain of anthrax that uses genes from *Bacillus Cereus*. The new strain is apparently able to overcome the protection offered by the Russian anthrax vaccine and it is therefore likely to be able to overcome the protection offered by the MBPI vaccine [9].

Recent analysis of tissue specimens from the bodies of victims of an explosion of a

bioweapons factory in Sverdlovsk in the former Soviet Union in 1979 indicated that DNA sequences from four different strains of anthrax were present. These strains may have been selected to overcome the protection offered by vaccines against anthrax [10,11,12]. Ken Alibek, a Russian defector, has alleged that the USSR had prepared genetically-altered strains of anthrax in order to circumvent the use of vaccines against them [13].

Safety

The potential risks to inoculated military personnel are still largely unknown. Sufficient small-scale testing of a similar vaccine convinced the FDA to license the current vaccine for use in protecting small numbers of at-risk workers [14]. But there are no published studies of the results of surveillance of vaccine recipients, and no data regarding long term side effects have been submitted to the FDA [15]. There is no reported experience with its use on a scale comparable to the inoculation of 2.4 million people. Experience with other vaccines that have been used widely after relatively small field trials indicates that unanticipated problems can develop in the course of massive use of approved drugs or vaccines.

Furthermore, inspections by FDA of the MBPI have revealed unacceptable manufacturing practices. The FDA had sent the MBPI a warning letter in 1995 and threatened to revoke its license in 1997 [16]. An FDA report of an inspection in February 1998 made dozens of serious charges regarding compliance problems, including contamination of the vaccine, reuse of outdated vaccines, and relabeling of lots that originally failed in order to place them in use [17]. The MBPI is now closed for renovation, but the vaccine being used by the Pentagon was produced while the unacceptable conditions were in place.

In May 1998 the Subcommittee on Human Resources of the Government Reform and Oversight Committee of the US House of Representatives began an investigation of the safety and efficacy of the MBPI vaccine and asked the US General Accounting Office (GAO) to conduct an independent probe. The GAO report is expected by the end of 1998. The Subcommittee is concerned that a 1987 Memorandum of Understanding (MOU) between the

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Anthrax: The Military View *(continued from page 98)*

ognized threat and we have a vaccine that can counter that threat that is safe, then we want to use it....

[A]nthrax [is] the poor man's atomic bomb. It's ubiquitous, it's everywhere, it's easy to get a hold of, it's easy to grow. And we don't have to go out and tell anybody about that. People already know that. So we have a very dangerous bacterium, very common and easy to get a hold of, and we have a very safe vaccine against it.

Q: How difficult a task is it to genetically engineer anthrax or anything else to circumvent this major effort you're making?

Dr. Bailey: Fortunately for vaccines, it is difficult to surpass or circumvent the effectiveness of the vaccine. We all know that you can develop resistance to antibiotics, for instance, but it's much more difficult to circumvent the vaccine.

Q: So this vaccine is effective against all the strains of anthrax that we know about right now?

Dr. Bailey: This vaccine is thought at this point to be effective against all the strains we know about....[E]ven though you see a long string of six injections, in fact, probably within two or three you've probably got a good antigen response and good protection.

Admiral Cowan: We're working very hard on other aspects of this....We have computer—polymerase chain reaction, PCR technology in the field now in Southwest Asia that can take very minute bits of organic material and rapidly replicate the DNA in that material until it reaches a point where we can identify it.

...We've made pretty substantial improvements in the protective devices...new lightweight masks and over-garments for chemical and biological protection...

And in the event of attack, where we think the possibility might be that some people's immune systems will be overwhelmed by a massive initial dose, then we have antibiotics, too, as a back-up system....

Q: Are there concerns of any resistant stains if the vaccine is stopped over time?

Admiral Cowan: If you expose a bacterium to antibiotics and don't kill it, just hurt it, it makes it stronger. And antibiotic exposure to bacteria has resulted in a number of different bacteria developing resistance to the antibiotics. The same is not true for this. Because the anthrax bug, the bacterium, goes in the body and is attacked by the antibodies, not the antibiotics. So it's the body's own immune defenses and the germs can't get a resistance. So that information applies to antibiotics but not to antibodies, not to vaccination.

Q: Can you talk about any other agents that are out there that may be threats and if there currently is a vaccine—or is this the only one?

Admiral Cowan: The important part of the answer, I think, is that we're working on a series of counter measures. One particularly promising one is a multi-valent vaccine where we're using new DNA technology to take the shell of a virus, empty out its own DNA, and then insert the target genetic material from any number of other bacteria and viruses that we would like to immunize

(continued on page 102)

Department of Defense and the Food and Drug Administration may be restricting FDA's oversight of the anthrax vaccine program. The Subcommittee Chairman asked the GAO to look into the extent to which the MOU might limit FDA review of the vaccine program; the extent to which claims regarding safety and efficacy of the vaccine are supported by data; and the extent to which problems identified by FDA at the MBPI could effect the safety and efficacy of the vaccine [18].

The Pentagon's record of conducting immunization programs in the past does not inspire confidence. For example, the Presidential Advisory Committee on Gulf War Veterans' Illnesses was sharply critical of the military's poor record-keeping on immunizations during the Gulf War. More recently, it characterized the Pentagon's efforts to improve its medical record keeping in Bosnia, where it used tick-borne encephalitis vaccine, as an "abysmal failure" [19,20]. Furthermore, the full House Committee on Government Reform and Oversight unanimously approved a report on November 7, 1997 that concluded, "DOD failure to adhere to record-keeping requirements [during the Gulf War] should result in the presumption of service connection for any subsequent illness to service personnel to whom the drug...was administered."

Closely related is the question whether the Pentagon conducted adequate record keeping and follow-up on the approximately 150,000 US troops who are reported to have received anthrax immunization during the Persian Gulf War. On September 8, 1991, just months after the Gulf War ended, the Army's Medical Research and Development Command prepared their "Update on Medical Biological Defense Vaccine Program." It proposed a follow-up study of a "unique pool of subjects" — those troops who received anthrax immunization. If the military indeed conducted research on this population, such data have not been released publicly so that impartial analysts can review them. If the US military had placed the highest priority on the safety and efficacy of this vaccine, it would have started with placebo-controlled, carefully-monitored trials limited to troops who are willing to give free and informed consent to be guinea pigs in such an experiment. If the military has ever conducted such a trial, the results have not been reported in the open, peer-reviewed literature.

Coercion

Another issue in military use of the MBPI vaccine lies in the fact that troops were ordered to take the vaccine without first giv-

ing their free and informed consent. Several members of the US armed forces are known to have refused inoculation with the anthrax vaccine. As of April 20, 1998, 14 sailors aboard two ships in the Persian Gulf were being punished for refusing to permit the inoculation and two Air Force airmen have also refused the vaccine and were also disciplined. After one of the sailors, Nhut M. Nguyen, aboard the aircraft carrier USS Independence, refused the vaccine, he was reduced in rank and was fined. He wrote to *Navy Times* that he was told that failure to have the inoculation could cost him his ability to receive US citizenship and could cause him to be thrown out of the Navy without any benefits. Nguyen wrote in one of his messages that many sailors are afraid of getting the vaccine but are even more frightened of the consequences of refusing [21].

The anthrax vaccine was also given to the roughly 300 members of the Canadian armed forces on the way to the Persian Gulf area [22]. The newspaper *Stars & Stripes* reported in March that a Canadian sergeant was facing disciplinary action for refusing an order to be vaccinated for anthrax [23]. The armed forces of the United Kingdom have also been offered anthrax immunization, but on a voluntary basis. Recent reports indicate that 73% of those offered the vaccine have refused to accept it [24].

A recent case indicates the length to which the US military has gone to insist that its troops accept the vaccine. US Army PFC Matthew Baker left his post at Fort Stewart, Georgia because, as he stated in a letter to the Surgeon General of the US Army, "I indicated my concerns about being given the anthrax vaccine and was told by my First Sergeant that if I refused to submit to an anthrax vaccine hypodermic shot, I would be strapped down to a gurney and would be forcibly injected against my will." In his letter Baker requested that a Court of Inquiry be convened to investigate the anthrax vaccination program.

While it is clear that individual civil rights may be constrained for those in military services and that international law has generally supported these constraints within certain bounds, it is not clear that a military service forcibly injecting its troops with a vaccine, whose safety and efficacy are in considerable dispute, would be considered lawful activity.

Ethics and Policy

In addition to the specific issues related to the use of the MBPI vaccine against anthrax, other risks in vaccine policies also loom large, such as the impact that use of

vaccines for inoculation of troops will have on the control of biologic weapons. In 1996 some military officials were concerned, according to the *Washington Post*, "that word the United States is about to embark on a program to defend against anthrax might be misread as a sign Washington has a secret offensive capability or intends to develop one."

Seymour Hersh, has recently reported [25] that one of the reasons the US military was concerned about the threat of use of anthrax in the Persian Gulf was evidence that Iraqi troops may have been immunized against anthrax. According to Hersh, one of the pieces of evidence that convinced the US military that Iraq might be planning to use anthrax as a weapon in the Persian Gulf War was the discovery that Iraqi soldiers captured in a US covert operation had immunity against anthrax. Hersh writes that "an elite American Special Forces team, operating deep inside Iraq before the war, had kidnapped some Iraqi soldiers and determined, from blood samples, that they had recently built up an immunity to anthrax.... It was not clear whether the Iraqis had been inoculated with anthrax vaccine or had developed immunity to the disease, which occurs naturally in the animal population in some areas of Iraq. It didn't matter. Military planning had to assume the worst—that the Iraqis would not be affected by a biologic attack."

In a world in which many nations are prepared to believe the worst about the military policies of other nations, information about immunization of the armed forces of a potential enemy may lead to destabilizing suspicions and unnecessary, costly, and risky countermeasures to possible bioattack. Action by the United States to immunize its troops is almost certain to persuade other nations to immunize theirs, thereby perpetuating a dangerous aspect of the biologic weapons race. There is also the long-recognized principle among planners of biologic weapons strategies that the surest way to cause a potential user to switch from biologic weapon A to biologic weapon B is to learn that the enemy's troops are immunized against A.

Moreover, immunizing troops with a vaccine that may be effective while leaving civilians unprotected comes dangerously close

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Anthrax: The Military View

(continued from page 100)

someone against and put it back in this virus, which is now not an infection but a viral capsule that carries the structures that we would like to immunize with. And then that becomes our immunization.

These things are emerging technologies. They're on the horizon. We don't have them at this point. But that's the sort of answer that we would like to come up with for all of these emerging threats.

Dr. Bailey: ...[P]art of the success of this program has been that, for the first time, we have a system that allows us to track exactly what is happening with these immunizations....[W]e know who received the immunization, who is on their second or third shot, who might be a week late. We know that down to the unit and we know it down to the individual.

Q: Have you worked out a formal policy about how to deal with those who refuse to take the shot?

Admiral Cowan: These are Service specific actions. Each Service has, under the UCMJ, the authority to deal with this, and each Service is dealing with it under the rubric of disobeying a lawful order. All of the people who have been disciplined so far have been disciplined in the non-judicial punishment. There have been no court martials.

Dr. Bailey: Of all these immunizations, the 48,000 people, we have only had 15 refusals.

Q: But that was in the Gulf, where there was sort of obviously a greater threat than other areas. Are you worried that once you start immunizing people at bases in the US that more people will say "I would rather not take this?"

Admiral Cowan: I think we may. If there's not an immediate threat and people are not so immediately concerned, that may happen. But our position is this is very safe. I've also taken it. I have absolutely—none of us have any concerns. And we think it's of the order of magnitude of saying to someone, "You have to wear your helmet. It's for your safety."

Dr. Bailey: I think the message here is that we have a very mobile force. They're moving at all times into threat areas and out of threat areas. So I think the message we want to get out today is this is a lethal weapon, we need to protect you, we have a safe vaccine that can do so.

to a violation of the Geneva Conventions, in that such a policy specifically puts civilians at risk. Indeed, immunizing troops may convince another nation or group desperate enough to use biologic weapons that it should attack unprotected civilians instead, perhaps in a clandestine manner so the attack cannot be traced and retaliation initiated.

One of the most important ethical problems arises if the vaccine is considered to be effective, but is actually not effective or has only limited effectiveness. Military commanders, believing the vaccine to be effective, may expose troops under their command to situations that might have been avoided if the mis-

leading impression of protection had not been generated. Furthermore, the troops themselves, feeling themselves to be protected, may take risks they would not otherwise take.

In recent months, another set of ethical issues has arisen because a number of publications have raised fears of bioterrorism. Many of these have been inaccurate and extremely alarmist. For example, a commentary in the *Lancet* suggested that inhalation anthrax was transmissible from an individual with the disease to others [26]. There is, however, no evidence that inhalation anthrax can be spread by person-to-person contact [27]. The fears caused by these reports have led to rehearsals for response to attacks on a series of US cities and proposals for stockpiling of vaccines and antibiotics. Hearings on the issue before a committee of the US Senate on June 2, 1998 included witnesses, however, who stated that US preparation for biologic defense is misguided because so much of the funding goes to the Pentagon instead of hospitals and doctors [28]. Among the issues raised were the question whether the funds spent on the drills and the stockpiling could be more effectively spent to prevent the consequences of bioterrorism by providing adequate public health measures, preventive medicine, and treatment for endemic illness to the population.

Another issue that must be faced is that of conflict of interest. Profit-making from the immunization programs may influence military decisions. An analysis of the decision-making process that led to the awarding of contracts for stockpiling of vaccines to protect against bioterrorism led the New York Times to question conflict of interest among those participating in the decisions who stand to gain financially from a decision to stockpile the vaccines [29]. On July 7, 1998, the State of Michigan approved the sale of the MBPI to an investment firm headed by a former Chairman of the Joint Chiefs of Staff, Admiral J. Crowe, Jr., who was an important supporter of President Clinton in the 1992 Presidential campaign. The state of Michigan had earlier announced that it had accepted a 25 million dollar bid from the firm, Bioport, a subsidiary of the Maryland-based corporation Intervac. The subsidiary is said to have been created specifically for investment in MBPI. Admiral Crowe, who served as Chairman of the Joint Chiefs under Reagan, and as Ambassador to the United Kingdom under Clinton, is a principal investor in Bioport. Crowe told United Press International that, "with the ongoing threat of biological attacks, sales of the anthrax vaccine could expand beyond the United States." "We think the market is going to be pretty

good," he stated. It is also of interest that the details of the contract that the Pentagon signed with MBPI to supply anthrax vaccine for all US military personnel remains secret, although the *New York Times* reports that Admiral Crowe's firm "now has an inside track on at least 60 million dollars in Pentagon contracts."

Furthermore, as weapons of mass destruction that are frequently described as "the poor nation's nuclear weapons," biological (and chemical) weapons cannot be considered in isolation from nuclear weapons. While both the Biological Weapons Convention and the Chemical Weapons Convention were negotiated and adopted without structural linkage to each other or to the treaties governing nuclear weapons, the ability to strengthen and enforce these agreements over the long term or, conversely, to prevent them from unravelling, depends upon embracing disarmament policies across the full range of weapons of mass destruction. Moreover, the incentives to develop, possess and, perhaps, use biological weapons and chemical weapons will remain strong as long as nations without nuclear arsenals perceive these weapons as equalizers of sorts. In short, the elimination of biological, chemical and nuclear weapons are, ultimately, essentially the same goal.

Conclusion

When facing this issue of vaccinating two-and-a-half million people in the short run, for reasons of safety, efficacy, and public concerns over the massive scope and potential risk of this program, the interests of military personnel as well as the public would be better served if researchers unaffiliated with the Pentagon were permitted to conduct further studies on the vaccine. The Pentagon should invite major civilian US public health agencies, including the Centers for Disease Control and Prevention and the National Institutes of Health and major non-governmental organizations such as the American Public Health Association, to participate actively in the design, testing, implementation, and oversight of this plan. It would be tragic if these agencies were only brought in later, as was done with nuclear bomb-test fallout and Agent Orange to write a post-mortem analysis.

In the longer term, in responding to the profound policy concerns raised by the continuing threat of biologic and chemical weapons, the US and the other nuclear powers must recognize their obligations to move toward the elimination of nuclear weapons. If the United States wishes to protect its troops

against biologic weapons, the best method would be to join in negotiating a Nuclear Weapons Convention and, in accordance with it, to dismantle the US nuclear capability. Only then will it be possible for all nations to enjoy effective protection against weapons of mass destruction.

Overall, there is little evidence that vaccines are an effective or ethical solution to the threat of biologic weapons.

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