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 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]

Anthrax

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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....[It] 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)
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)

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

[Anthrax 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)
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, Nhu 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.
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 immu-
nization.

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 emerg-
ing 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. We 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
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 vac-
cine that can do so.

leading impression of protection had not been
generated. Furthermore, the troops them-
selves, 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 publi-
cations have raised fears of bioterrorism.
Many of these have been inaccurate and
extremely alarmist. For example, a com-
mentary in the Lancet suggested that inhalation
anthrax was transmissible from an individual
with the disease to others [26]. There is, how-
ever, 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 hos-
pitals 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 con-
sequences of bioterrorism by providing ade-
quate 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 mili-
tary decisions. An analysis of the decision-
making process that led to the awarding of
contracts for stockpiling of vaccines to pro-
tect 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 for-
ermer 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 corpora-
tion 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 vac-
cine 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 unraveling, 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.

References