

Testimony

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CHEMICAL AND
BIOLOGICAL DEFENSE

Observations on DOD's
Plans To Protect U.S. Forces

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Mr. Chairman and Members of the Committee:

We are pleased to be here today to discuss the Department of Defense's (DOD) continuing efforts to protect U.S. military forces against chemical and biological weapons, including its plan to inoculate all U.S. military forces against anthrax. As we learned from the Gulf War, U.S. forces were inadequately prepared for surviving and operating in a chemically or biologically contaminated environment. More recently, we found that deficiencies in medical record-keeping have hampered the conduct of epidemiological research to the point that DOD cannot provide precise, accurate, and conclusive answers regarding the causes of Gulf War veterans' illness.

Today, we will first briefly discuss the fundamental shortcomings in DOD's protection of its forces against chemical and biological warfare.¹ Then, we will discuss DOD's proposed anthrax immunization program.

Summary

In examining DOD's experience in preparing its forces to defend against potential chemical and biological agent attacks during the Gulf War, we identified numerous problems. Specifically, we found shortages in individual protective equipment, inadequate chemical and biological agent detection devices, inadequate command emphasis on chemical and biological capabilities, and deficiencies in medical personnel training and supplies.

While many deficiencies noted during the Gulf War remain unaddressed today, DOD has increasingly acknowledged and accepted the urgency of developing a capability to deal with the chemical and biological threat to its forces. Both the Congress and DOD have acted to provide greater protection for U.S. forces. Their actions have resulted in increased funding, and the fielding of more and better chemical and biological defense equipment. DOD must address remaining critical deficiencies if U.S. forces are to be provided with the resources necessary to better protect themselves. For example, DOD needs to decide on major policy and doctrine issues, improve and increase its capability to detect toxic agents, provide forces with improved and sufficient numbers of individual protective equipment, and deal with problems of collective protection and decontamination.

¹Appendix I provides a list of the unclassified GAO reports on DOD's chemical and biological capabilities. We have also issued three classified reports on this topic.

DOD is now embarking on a major effort to protect U.S. forces from the threat of the deadly biological agent anthrax. Its program to immunize millions of active and reserve forces against anthrax, ensuring that each receives the prescribed vaccinations in the proper time sequence, will be a challenge. However, if DOD considers lessons learned from previous, smaller-sized immunization programs and from the medical record-keeping errors in the Gulf War and in Bosnia in formulating detailed implementation plans, it can reduce the risks and improve the prospects for successfully managing the program.

Protecting Forces Against Chemical and Biological Agents Poses Continuing Challenges

In 1996, we reported that military units then designated for early deployment faced many of the same chemical and biological defense problems that Gulf War veterans had experienced.² During the Gulf War, units and individuals deployed to the theater without all of the chemical and biological detection, decontamination, and protective equipment needed to operate in a contaminated environment. Some units did not have sufficient quantities or the needed sizes of protective clothing, and chemical detector paper, and decontamination kits in some instances had passed their expiration dates. While the 6-month Operation Desert Shield buildup time allowed DOD to correct some of these problems, had chemical or biological weapons been used during this period, some units might have suffered significant, unnecessary casualties.

We further reported that DOD's progress in chemical and biological research and development was slower than planned, training of Army and Marine Corps forces was inadequate, there was little evidence that joint training and exercises included chemical and biological defense elements, stocks of vaccines for biological agents were in short supply, and medical units lacked necessary chemical and biological defense equipment and training. We believe these deficiencies were a result of, and would not be corrected without, changes in emphasis on the part of senior military leadership.

We have also reviewed DOD's ability to protect critical ports and airfields overseas. Although I cannot fully discuss our findings in this open hearing because of their sensitive nature, I can say that there are deficiencies in doctrine, policy, equipment, and training for the defense of critical ports and airfields.

²Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems (GAO/NSIAD-96-103, March 29, 1996).

The Congress and DOD have taken action that has improved U.S. forces' ability to survive and operate if chemical and biological agents are used against them. For example, DOD has requested and the Congress has approved increased funding for chemical and biological defense. Numerous efforts are currently underway that should provide our servicemembers with new chemical and biological defense equipment and capabilities over the next 5 years. These include the production and fielding of improved protective masks, body garments, and systems to better detect biological and chemical agents. In addition, several commanders in chief recently increased their emphasis on various aspects of chemical and biological defense by, for example, increasing stocks of chemical defense equipment and incorporating more chemical and biological defense scenarios in major military exercises.

Still, DOD must address remaining critical deficiencies that affect its ability to protect forces from chemical and biological attack. DOD's doctrine and policy are inadequate regarding responsibility for the chemical and biological defense of overseas airfields and ports critical to the deployment, reinforcement, and logistical support of U. S. forces in the event of a conflict. As a result, questions are unresolved regarding the provision of the force structure and equipment needed to protect these facilities. Also, unresolved doctrinal, policy, and equipment questions persist regarding the return of chemically or biologically contaminated strategic lift aircraft and ships and the protection of both essential and nonessential civilians in high-threat areas overseas. Moreover, DOD has insufficient quantities of biological agent vaccines to protect U.S. forces, and servicemembers deployed in high-threat areas overseas normally have no biological agent detection capability. Also, collective protection facilities and equipment and agent detection systems are generally insufficient to protect the force.

DOD's Program to Immunize Forces Against Anthrax

Anthrax is an infectious disease that afflicts certain animals, especially cattle and sheep. The anthrax vaccine was licensed by the Food and Drug Administration (FDA) in 1970 to protect veterinarians, meat packers, wool workers, and health officials who might come in contact with anthrax. (FDA licensure of a vaccine means that it has been tested and proven to be safe and effective in humans.) The vaccine has been routinely administered to populations at risk for several years.

The Chairman of the Joint Chiefs of Staff considers anthrax to be the greatest biological weapons threat to U.S. military forces. After a 3-year

study, the Secretary of Defense concluded that vaccination is the safest way to protect U.S. forces against a threat that is 99-percent lethal to unprotected individuals. Accordingly, in December 1997, DOD announced plans to vaccinate all U.S. military personnel (including active, reserve, and national guard servicemembers) against the biological warfare agent anthrax. The Michigan Biologic Products Institute is under contract with DOD to supply the vaccine for the DOD immunization program.

While the vaccine will be centrally procured, administering the vaccinations will be decentralized at multiple DOD facilities worldwide. Initially, DOD planned to begin administering the program in the summer of 1998 to about 165,000 servicemembers and DOD mission-essential personnel located in Southwest Asia and Northeast Asia, which are the areas with the greatest biological warfare threat from anthrax. Prior to beginning the immunizations, DOD wanted time to (1) perform testing of the vaccine to ensure its sterility, safety, potency, and purity; (2) implement a system to track personnel who receive the vaccinations; (3) approve plans to administer the immunizations and inform military personnel of the program; and (4) have the program reviewed by an independent expert. However, DOD accelerated the anthrax vaccination schedule. In March 1998, DOD began immunizing forces stationed in the Persian Gulf because of the possibility of hostilities occurring in that region. DOD plans to vaccinate the remaining active and reserve force over the next several years. In addition, DOD plans to decide whether the program should be extended to others, such as host nation personnel, civilian contractors, and dependents.

In accordance with the FDA licensure regimen for this vaccine, DOD plans to provide an initial series of three vaccinations at 2-week intervals, a second series of three vaccinations at 6-month intervals, and annual booster vaccinations to maintain immunity against anthrax. DOD recognizes that immunizing the entire force with multiple vaccinations will be difficult and involves significant administrative and logistical issues. DOD's program will involve administering anthrax vaccinations to about 2.4 million personnel around the world—a total of about 14.4 million vaccinations for the current force. In addition, personnel entering military service will also be immunized. Thus, DOD envisions the program to continue indefinitely.

Personnel Data Systems to Identify Servicemembers Requiring Vaccinations Must Be Accurate

To ensure that all servicemembers receive the required vaccinations, it is important for DOD to have accurate and reliable personnel data systems showing where all servicemembers are located, especially those deployed to overseas locations.

Our work in examining the Operation Joint Endeavor medical surveillance program in Bosnia surfaced concerns about the accuracy of the deployment database used for determining which servicemembers required postdeployment medical assessments. More specifically, DOD officials expressed concerns about the accuracy of the DOD-wide database that was used to identify Air Force and Navy personnel who deployed to Bosnia. Air Force officials told us that the Air Force had supplied information to DOD's database on servicemembers it planned to deploy but that many of them never deployed and the database was not corrected. We were also told that data on servicemembers assigned to two Navy construction battalions that deployed to Bosnia did not appear in the database. DOD officials told us that they were concerned about the accuracy of the deployment database and planned to address the problem.

Sufficient Command Emphasis Needed to Ensure Program Implementation

Because DOD plans to administer anthrax vaccinations in a decentralized manner at multiple locations involving both operational and medical personnel, high-level commanders need to emphasize the importance of the program to ensure that it is carried out within the time schedule for administering the vaccinations. Careful attention to the administration of vaccines is critical because the vaccinations must be given at specific intervals over an 18-month period to achieve maximum protection.

In the past, a lack of command emphasis hindered DOD's successful implementation of medical programs. For example, we found that the Army had not done many postdeployment medical assessments of active duty personnel who had deployed to Bosnia. We also found that assessments done were, on average, not done within the 30-day time frame DOD established. Our work disclosed that it took an average of 98 days to complete the assessments.

In addition, the Bosnia medical surveillance plan also required servicemembers to undergo a tuberculin test at about 90 days following departure from the theater. Our work disclosed that the test took an average of 142 days.

These problems occurred because command officials did not emphasize the importance of the assessments and medical personnel did not have the authority to require servicemembers to go to medical clinics for assessments. Reliance upon unit commanders to require servicemembers to get the assessments was not effective for the Bosnia deployment.

Medical Records Documenting Vaccinations Must Be Complete

Medical records documenting all care (including vaccinations) for servicemembers are essential for the delivery of high-quality medical care. DOD regulations require documentation in a servicemember's permanent medical record of all immunizations and visits made to health units.

The Presidential Advisory Committee on Persian Gulf War Veterans' Illnesses and the Institute of Medicine reported problems concerning the completeness and accuracy of medical record-keeping during the Gulf War. Research efforts to determine the causes of what has become known as veterans' Gulf War illnesses have been hampered by, among other things, incomplete medical records showing immunizations and other health services provided to servicemembers while deployed. The Institute of Medicine characterized DOD's medical records as fragmented, disorganized, and incomplete.

We tested the completeness of medical records for selected active duty Army servicemembers who had deployed under Operation Joint Endeavor. We found that many of the medical records were incomplete in that they lacked documentation on (1) medical surveillance assessments conducted, (2) tick-borne encephalitis vaccinations given, and (3) visits made to in-theater health units. More specifically, we found that 19 percent of the postdeployment in-theater medical assessments and 9 percent of the postdeployment home unit medical assessments were not documented in the medical records. These documentation problems were attributed to the fact that this was a paper-based system that relied upon servicemembers to hand carry assessment forms from the theater to their home unit, which maintained the permanent medical record.

Regarding the documentation of tick-borne encephalitis vaccine in Bosnia, servicemembers deploying to regions where the threat of this disease was prevalent were given the choice of being inoculated with this investigational drug vaccine.³ We found that 141 (24 percent) of the 588

³An investigational drug is a new drug or product regulated by FDA that has not been licensed for general use in the United States.

medical records reviewed for servicemembers who had received the vaccine lacked required documentation.

Our tests of the completeness of the permanent medical records for servicemembers' visits made to battalion aid stations in Bosnia showed similar problems. Specifically, we found that there was no documentation in the medical records for 44 (29.3 percent) of the 150 visits we reviewed. Army officials mentioned that permanent medical records were still paper-based and that information was subject to being misfiled or lost. They also pointed out that servicemembers had deployed to the theater with only an abstract of their permanent medical records and that any medical documentation generated in the theater was to have been routed back to the servicemembers' home units for inclusion into their medical records.

DOD officials told us that a solution to these documentation problems would be the development of a deployable, computerized patient record. DOD has a project underway to have a paperless computerized medical record for every active duty servicemember by fiscal year 2000.

Centralized Database for Monitoring Program Implementation Must Be Accurate

Without an adequate centralized monitoring system, DOD will not have reasonable assurances that the program is being implemented as planned. For Operation Joint Endeavor, DOD established a centralized database to track the services' progress in implementing its medical surveillance program. Medical units processing medical assessments were required to send copies of assessment forms to the DOD office maintaining the centralized database in the United States.

In testing the completeness of the centralized database for in-theater and home unit postdeployment medical assessments conducted for 618 servicemembers, we found that the database understated the number of assessments done. More specifically, it omitted 12 percent of the in-theater medical assessments and 52 percent of the home unit medical assessments.

DOD officials told us that they plan to use a new automated system for tracking implementation of the anthrax immunization program from locations around the world. The automated system is still being developed.

Efficient Inventory Controls Are Necessary to Ensure Sufficiency of Vaccine Supply

To ensure that military personnel will receive vaccinations in a timely manner and to effectively manage the program, it is important for DOD to maintain an efficient inventory control system. This system is needed to ensure that (1) sufficient supplies of vaccines will be available at the various worldwide immunization sites; (2) vaccines that are older than their 1-year shelf life are destroyed; and (3) records of vaccines received, administered, and destroyed are kept to allow for monitoring and tracking.

For the Bosnia deployment, DOD experienced problems in accounting for the inventory of the tick-borne encephalitis vaccine. DOD had to comply with strict FDA regulations regarding its use because it was still being tested as an investigational new drug. Regulations required DOD to fully account for vaccine inventories, including the number of doses administered and the number of doses destroyed.

In the spring of 1996, officials from the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) went to Bosnia to review the procedures being used to administer the tick-borne encephalitis vaccine. These officials found that no record of vaccine disposition was being maintained and recommended that all vaccination sites perform a physical inventory and maintain data on vaccines on hand, used, and destroyed. USAMRIID officials met with considerable resistance from some medical personnel responsible for administering the vaccine about the need to keep proper records. They told us that some of the personnel seemed more interested in administering the vaccine than in keeping necessary records.

Our work on the Bosnia deployment in 1997 showed that the problems identified by USAMRIID had not been corrected. More specifically, DOD could not account for more than 3,000 (20 percent) of the total number of doses sent to Bosnia. Since our report was issued in April 1997, officials from the Office of the Army Surgeon General informed us that most of the missing doses had been destroyed and only 242 doses remained unaccounted for.

Conclusions

In conclusion, we believe that DOD has moved in the right direction in increasing its emphasis on improving its chemical and biological defense capabilities. Increased emphasis by the commanders in chief in their areas of responsibility, a DOD-wide spending increase leading to increased numbers of fielded chemical and biological detection and protective equipment, and planned procurements of equipment over the next several years will make U.S. forces better prepared to deal with chemical and

biological weapons than in the past. However, greater diligence and more action is needed by DOD to maintain progress toward achieving a level of protection for our forces that will enable us to achieve wartime objectives. This latest initiative to immunize the forces against anthrax represents a clear recognition of this threat to U.S. servicemembers. But DOD must overcome past deficiencies in its medical record-keeping practices and make sure supplies of vaccine are available if this new program is to be successful. In this regard, we reiterate that DOD needs to have the means to (1) identify those servicemembers that require immunization, (2) ensure sufficient command emphasis to guarantee that those identified for immunization are immunized, (3) maintain an accurate medical record of immunizations for each servicemember, (4) manage large-scale immunizations through accurate central databases, and (5) ensure that vaccine inventories are appropriately controlled to ensure that sufficient supplies are on hand.

This concludes my prepared remarks. We would be happy to respond to any questions the Committee may have.

Related GAO Reports on Chemical and Biological Defense

Gulf War Illnesses: Public and Private Efforts Relating to Exposures of U.S. Personnel to Chemical Agents ([GAO/NSIAD-98-27](#), Oct. 15, 1997).

Combating Terrorism: Status of DOD Efforts to Protect Its Forces Overseas ([GAO/NSIAD-97-207](#), July 21, 1997).

Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis Are Needed ([GAO/NSIAD-97-163](#), June 23, 1997).

Defense Health Care: Medical Surveillance Improved Since Gulf War, but Mixed Results in Bosnia ([GAO/NSIAD-97-136](#), May 13, 1997).

Chemical and Biological Defense: Emphasis Remains Insufficient to Resolve Continuing Problems ([GAO/NSIAD-96-103](#), Mar. 29, 1996).

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