

GAO

Testimony

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ANTHRAX VACCINE

Preliminary Results of  
GAO's Survey of  
Guard/Reserve Pilots and  
Aircraft Members

Statement of Kwai-Cheung Chan, Director  
Applied Research and Methods



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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the preliminary results of the ongoing work we are doing at your request on the Department of Defense's (DOD) Anthrax Vaccine Immunization Program. As you know, numerous concerns have been raised about the program since DOD began vaccinating its 2.4 million active duty and reserve members in 1998.<sup>1</sup> Of particular concern was the program's potential impact on the Air National Guard and Air Force Reserve's retention of trained and experienced personnel.

In response to your request, we are examining the impact of the vaccination program on retention, the basic views of Guard and Reserve pilots and other aircrew members regarding the program, and the extent of adverse reactions experienced by anthrax vaccine recipients. These components provide essential support to critical defense operations on a worldwide basis. They provide strategic and tactical airlift, aerial refueling, aeromedical evacuation, and augment DOD's overall fighter force.

To conduct our work, we developed, pre-tested, and validated a questionnaire that was sent to 1,253 randomly selected Guard and Reserve pilots and other aircrew members. These included pilots, flight engineers, loadmasters, navigators, crew chiefs, and others. Collectively, they represent about 13,000 servicemembers of the total fiscal year 1999 end strength of approximately 176,000, which includes about 29,000 officers and 147,000 enlisted personnel. We shared the draft questionnaire with DOD program officials and their medical experts and incorporated appropriate comments and suggestions. We administered the survey on an anonymous basis between May and September 2000. The overall response rate was 66 percent. Our methodology is described in detail in appendix I. The information we are presenting today has been weighted to represent the population of Guard and Reserve pilots and other aircrew members who are currently active and assigned to a unit.

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## Summary

While many factors can influence an individual's decision to leave the military, surveyed Guard and Reserve pilots and aircrew members cited the anthrax immunization as a key reason for leaving or otherwise changing their military status. Since September 1998, an estimated

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<sup>1</sup> We have previously reported on a number of concerns regarding the safety and efficacy of the anthrax vaccine and other related matters. (See appendix III).

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25 percent of the pilots and aircrew members of the Guard and Reserve in this population transferred to another unit (primarily in a non-flying position), left the military, or moved to inactive status. While several reasons influenced their decision, when asked to rank the one most important factor, the anthrax immunization was the highest, followed by other employment opportunities, and family reasons. Further, about one in five (18 percent) left before qualifying for military retirement benefits. Additionally, 18 percent of those still participating in or assigned to a unit reported their intentions to leave within the next 6 months. These individuals also ranked the anthrax immunization as the most important factor for their decision to leave, followed by unit workload and family reasons. Each of these groups—those who have left and those who plan to do so—had accumulated an average of more than 3,000 flight hours, which symbolizes a seasoned and experienced workforce.

On our survey, most Guard and Reserve pilots and aircrew members expressed a positive view toward general immunizations. Almost three out of four believe that immunizations are effective (74 percent), and more than half believe immunizations to be safe (60 percent). However, their views on the anthrax immunization program and potential biological warfare immunizations in the future are very different. For example, two out of three reported little or no support for the anthrax program (65 percent). Despite DOD's high-visibility campaign to educate servicemembers about the anthrax immunization program, only about one in four believes that the information provided on DOD's anthrax Web site is timely (25 percent), 19 percent believe it to be complete, and 17 percent believe it to be accurate. Just 1 in 10 (11 percent) believe the information to be unbiased. Further, three out of four indicated they would not or probably would not take the shots if the anthrax immunization program were voluntary (76 percent). Eighty-seven percent, or almost 9 out of 10, indicated they would or probably would have safety concerns if additional vaccines for other biological warfare agents were added to the military immunization program.

Forty-two percent of the respondents reported that they had received one or more anthrax shots. Of those taking the shots, 86 percent reported experiencing some type of local or systemic reactions, for example, a knot in the arm or joint pain. For some reactions, the reported duration was more than 7 days (for example, limited arm/body motion and joint pain). Some of these reactions could have implications for work performance. About one-third (36 percent) reported that they had been provided information concerning what action to take in the event of side effects or reactions. But 71 percent reported being unaware of the Food and Drug Administration's Adverse Events Reporting System which is a passive

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surveillance system to alert the Food and Drug Administration and the Center for Disease Control and Prevention of adverse events that may be associated with licensed vaccines. Further, about 60 percent of those experiencing reactions had not discussed them with military health care personnel or their supervisors—some citing fear of the loss of flight status, possible adverse effects on their military or civilian careers, and ridicule as reasons for nondisclosure (49 percent).

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## Background

In December 1997, the Secretary of Defense announced that all U.S. forces would be inoculated against the potential use of anthrax on the battlefield. In August 1998, DOD began immunizing its 2.4 million U.S. military personnel—including active and reserve component personnel—with a licensed anthrax vaccine. This program is mandatory. Some members of the armed forces have expressed concerns regarding the safety and efficacy of the anthrax vaccine. Those refusing the vaccine have been disciplined under service-specific policies for disobeying a lawful order. Anecdotal information suggests that an unknown number of Reservists and National Guard members have resigned or transferred to units or non-flying positions that do not require anthrax vaccinations at this time. DOD does not collect uniform records on such changes in status.

Congress and the Department of Defense have become increasingly concerned about the readiness of U.S. armed forces. Key reasons for this concern are the increasing pace (tempo) of operations due to deployments, parts shortages and maintenance backlogs, and past problems in recruiting and retaining quality people. The reserve components are experiencing difficulties in filling their ranks with new recruits at a time when DOD is relying on them more heavily to support operations around the world. Specifically, the retention of pilots and other aircrew members has been and continues to be a problem that could impact readiness. The impact of an exodus of Guard and Reserve pilots and aircrew members would be significant. Without adequate numbers of pilots and aircrew, the Guard and Reserve could not support the active force in its worldwide operations. In addition, it costs the military an average of almost \$6 million to train and develop a fully qualified experienced aviator, which the Air Force suggests takes about 9 years.

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## Anthrax Is a Key Factor Affecting Individual Decisions to Change Military Status

Twenty-five percent of the pilots and aircrew members of the Guard and Reserve we surveyed have transferred to another unit, left the military, or moved to inactive status. Of these, 25 percent ranked anthrax immunization as the most important factor influencing their decision to leave or transfer followed by other employment opportunities at 16 percent and family reasons at 16 percent. The general military immunization program was cited as the least important reason for a change in their military duty status. Further, about one in five (18 percent) left before they had qualified for a military retirement. Forty-three percent of those who separated or are no longer in military flying status because of the anthrax program indicated that they would or probably would consider returning to a unit or to military flying status if the anthrax vaccination program were not mandatory.

Of those who are still in Guard and Reserve units, 18 percent reported that they planned to leave the military within the next 6 months. Again, when asked to rank the most important factor for their decision to leave, the anthrax immunization was the most frequently reported reason (61 percent), followed by heavy unit workload and family reasons. Each of these groups (that is, those who left and those who intend to leave) had in excess of 3,000 flight hours, which symbolizes a seasoned and experienced workforce.

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## Anthrax Vaccine Immunization Program Is Not Widely Supported

Most Guard and Reserve pilots and aircrew members support immunization programs in general; however, relatively few appear to support the anthrax program or future immunization programs for other biological warfare agents. Almost three out of four (74 percent) of the pilots and aircrew members of the Guard and Reserve believe that immunizations in general are moderately to very effective, and 60 percent believe that immunizations are moderately to very safe. On the other hand, 65 percent, or two out of three servicemembers, reported little or no support for the anthrax immunization.

DOD has employed a high-visibility campaign to educate servicemembers about the program and has taken steps to address the controversy surrounding the program. In addition, it expanded its communications efforts by updating the program's Internet site, opening a toll-free anthrax information line and forming a speakers' bureau of anthrax experts. DOD also updated briefings for installation leaders and medical personnel to provide more detailed information on the anthrax threat. We had previously reported in October 1999 that servicemembers were not

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satisfied with the information provided to them.<sup>2</sup> In our current survey, relatively few respondents reported being moderately to very satisfied with the information provided at the DOD Web site. For example, only 19 percent were satisfied with the completeness of the information 17 percent were satisfied with the information's accuracy, and 25 percent were satisfied with its timeliness. Just 11 percent were satisfied that the information was unbiased.

In terms of all information provided by DOD to servicemembers on the anthrax program through the Web site and other sources, 39 percent indicated that they were moderately to very satisfied with the information provided on the military anthrax threat. On the other hand, only 12 percent were moderately to very satisfied with the information received about the vaccine's long-term safety.

Seventy-six percent of survey respondents indicated that they would not or probably would not take the shots if the anthrax immunization program were voluntary. Just 11 percent reported they would or probably would take the shot on a voluntary basis. About 13 percent were uncertain. Further, 87 percent reported that they would or probably would have concerns about safety if additional vaccines for other biological warfare agents were added to military immunization requirements.

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## Most Adverse Events to Anthrax Immunizations Are Not Reported

Adverse events are adverse outcomes for which a cause and effect relationship with an exposure (to a vaccine or a medication) has not yet been determined. DOD has used data from the Vaccine Adverse Event Reporting System to monitor adverse events (or reactions) to anthrax vaccinations. It is a "passive" surveillance system, which relies on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine. Studies show that significantly fewer adverse events are reported under a passive system when compared to an active surveillance system in which vaccine recipients are actively monitored to identify and track any adverse reactions to a vaccine.

Forty-two percent of the respondents reported that they had received one or more anthrax shots. Of these, 86 percent reported experiencing side effects or adverse reactions. About 60 percent indicated that they had not discussed any side effect to the anthrax vaccine with military health care personnel or their supervisors—some (49 percent) citing as their reasons

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<sup>2</sup>Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/NSIAD-00-36, October 1999).

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fear of losing their flight status, adverse effects on their military or civilian careers, and ridicule. Seventy-one percent reported that they were unaware of the Food and Drug Administration's Vaccine Adverse Events Reporting System. Slightly less than 6 percent of those who had a reaction reported to this system.

Our survey showed that for some local and systemic reactions (for example, a knot or lump in the vaccinated arm and joint pain), the reported duration was more than 7 days. (See table 1 in app. II for a list of reported reactions). The prevalence and duration of the reported symptoms varied widely. A number of reported symptoms are expected reactions to the anthrax vaccine; however, their frequency and duration was more than DOD reported (0.007 percent). For example, two out of three reported burning in the vaccinated arm (79 percent) and a knot or a lump in the vaccinated arm (82 percent). Also, 10 percent reported swelling in the arm lasting for more than 7 days, and 6 percent reported arm pain and limited motion for more than 7 days. Six percent reported extreme fatigue, and 7 percent reported joint pain lasting for more than 7 days.

These reported reactions are significant because they could potentially impact individual ability to carry out military duties. However, 60 percent of those who experiencing reactions had not discussed them with military health care personnel or their supervisors. Forty-nine percent did not report because the reactions were not severe enough; however, another 49 percent did not report because of the fear of losing flight status, possible adverse effects on their military and civilian careers, and a fear of ridicule. Since many individuals are not reporting their reactions to military medical personnel or to the Vaccine Adverse Events Reporting System, the actual duration, the extent or impact on units and individuals, and the ultimate resolution of these reactions are unknown.

Because we had limited time to analyze all of the data we obtained, we will provide additional detailed analyses of the data to the Committee in a later report. Other issues such as impact of anthrax vaccine program on morale and quality of life will also be addressed in that report.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you have at this time.

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## Contacts and Acknowledgments

For future questions regarding this testimony, please contact Kwai-cheung Chan at (202) 512-3652. Other individuals making key contributions to this testimony includes Sushil K. Sharma, Ph.D., DrPH, Foy D. Wicker and Stanley J. Kostyla.

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# Scope and Methodology

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The best way to reliably assess the pulse and views of military members is by surveying a representative sample of personnel. This year, we developed and administered such a survey that was designed to obtain the views of selected Air National Guard and Air Force Reserve personnel regarding issues associated with the DOD's Anthrax Vaccine Immunization Program (AVIP). The survey was mailed in May 2000 to a random sample of 1,258 personnel. As of September 7, 2000, 829 individuals had completed and returned the survey. Our work was conducted in accordance with generally accepted government auditing standards.

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## Questionnaire Development

The survey was developed with the assistance of discussion groups made up of pilots and other aircrew members of the Air National Guard and Air Force Reserve. It was pretested at Andrews Air Force Base, Maryland, and further pretested and refined at Guard and Reserve units located in Hartford, Connecticut; Newburg, New York; Madison, Wisconsin; Battle Creek Michigan; Memphis, Tennessee; Travis Air Force Base, California; March Air Force Reserve Base, California; Fort Wayne, Indiana; and, Dover, Delaware

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## Sample Construction

The sample consisted of 1,253 Air National Guard and Air Force Reserve aircrew personnel who were in the service at any time between September 1998 and February 2000. Our sample was drawn from pilot and aircrew member populations provided by the Air National Guard and Air Force Reserve in early 2000. In addition the Anthrax Vaccine Immunization Program Office provided information as to vaccination status. For the sample design, personnel in our universe were categorized by two factors: military status (left versus on board) and vaccine status (shot versus no shot). The sample was adjusted for groups with differing expected rates of survey completion and adjusted to provide a level of precision of  $\pm 7$  percentage points.

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## Survey Administration

As of September 7, 2000, we had received 828 responses from eligible respondents, an overall response rate of 66 percent. We used a contractor to create a database based on reported responses. We validated the data provided to us by the contractor to ensure accuracy.



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## Weighting Responses and Potential Nonresponse Bias

The survey responses were weighted to reflect the Air National Guard and Air Force Reserve population for the survey. This weighting procedure adjusts for the different proportions of individuals sampled from each cell and the actual response rate for that cell in the sample design. The survey results assume that nonrespondents would have answered like respondents. This assumption involves some unknown risk of nonresponse bias. Weighting can be used to statistically adjust for differing sampling rates and response rates; however, weighting cannot adjust for possible differences between those who do and those who do not respond to a survey.

# Prevalence of Local and Systemic Adverse Reactions by Duration

Type of reaction	< 1 Day	1-3 Days	4-7 Days	> 7 Days	Total
Local	Percent	Percent	Percent	Percent	Percent
Redness 2.5 inches or less	21	20	7	5	53
Redness >2.5 inches	5	12	10	6	33
Swelling in arm	16	18	11	10	55
Burning in arm	60	14	3	2	79
Arm Pain limited motion	20	22	11	6	59
Itching in arm	18	10	7	5	40
Knot/lump in arm	17	14	21	30	82
<b>Systemic</b>					
Chills	5	4	3	1	13
Fever	7	6	2	1	16
Extreme fatigue	6	7	3	6	22
Dizziness	1	2	1	1	5
Headaches	6	6	2	1	15
Blurred vision	1	1	0	1	3
Numbness in extremities	3	1	1	2	7
Joint pain	6	5	5	7	23
Memory loss	1	1	1	2	5
Blackouts	0	0	0	0	0
Ringing in ears	2	1	1	2	6
Insomnia	1	1	2	1	5
Nausea	3	2	2	0	7
Other	1	1	2	3	7

Source: GAO Survey, 2000.

Gulf War Illnesses: Questions About the Presence of Squalene Antibodies in Veterans Can Be Resolved (GAO/NSIAD-99-5, Mar. 29, 1999).

Medical Readiness: Safety and Efficacy of the Anthrax (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Contract Management: Observations on DOD's Financial Relationship with the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

Medical Readiness: Issues Concerning the Anthrax Vaccine (GAO/T-NSIAD-99-226, July 21, 1999).

Anthrax Vaccine: Safety and Efficacy Issues (GAO/T-NSIAD-00-48, Oct. 12, 1999).

Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/NSIAD-00-36, Oct. 1999).

Medical Readiness: DOD continues to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program (GAO/T-NSIAD-00-157, Apr. 2000).

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