ANTHRAX VACCINE IMMUNIZATION PROGRAM

Threat, Effectiveness, Safety, & Supply

STATEMENT BY

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Submitted To

SENATE ARMED SERVICES COMMITTEE

SECOND SESSION, 106TH CONGRESS

JULY 12, 2000

INTRODUCTION

Chairman Warner and Distinguished Committee Members, we are honored to appear before your Committee today to address your questions on the Department of Defense (DOD) Anthrax Vaccine Immunization Program (AVIP). I am accompanied today by Mr. David Oliver, Principal Deputy Under Secretary of Defense for Acquisition and Technology, Admiral J. Jarrett Clinton, First Assistant to the Secretary of Defense for Health Affairs, and Major General Randall L. West, the Senior Advisor for Chemical and Biological Protection.

BACKGROUND

Late in 1997, Secretary Cohen accepted the recommendation of the Joint Chiefs to require vaccination of all U.S. military personnel against anthrax – a deadly biological agent which is almost always lethal to unprotected, untreated victims. Once inhaled, this colorless, odorless, and tasteless aerosolized weapon does not immediately become symptomatic. And even when the initial symptoms are manifested, they mimic a cold or flu. But, once these symptoms occur, it is too late for the vast majority of those contaminated. To protect our men and women against this lethal disease, the Department established a three-phase program in May 1998 that was designed to begin with those most at risk.

For the past two years, Phase 1 of the program has vaccinated those military members who are deploying to Southwest Asia and Korea, the two most likely regions where anthrax could be used against U.S. Forces.

To date, we have provided more than 1.8 million safe and reliable vaccinations – using a vaccine licensed by the Food and Drug Administration with a 30-year history of safe and effective use; every dose meeting the highest quality and safety standards; and backed by additional testing.

I would also point out that the Chairman of the Joint Chiefs, General Shelton, Secretary Cohen, former Deputy Secretary John Hamre, and I were among the very first to receive this vaccine.

When we began this program, we were using vaccine from our medical stockpile. The Michigan facility that produced the vaccine has since been sold and replaced by a new company, which is working to receive FDA approval to begin vaccine production at a new facility.

To date, all vaccinations given have used stockpile vaccine. We are beginning to run low on tested and certified doses from the stockpile, however, forcing us to temporarily re-focus our vaccination efforts. We will make every effort to continue vaccinating members who would be at greatest risk. And we will continue vaccinations in those areas as long as possible.

The rest of our force health protection package – such as detectors in the field and full supplies of antibiotics- will, of course, remain in place.

Let me give you an update on our Anthrax Vaccine Immunization Program, our efforts to acquire new vaccine, and a current assessment of the biological warfare threat as it relates to anthrax. I will begin by covering some contractual steps we have taken since we last appeared before this committee.

STEPS TAKEN

First, we have provided Defense Contract Management oversight and separate company consultants to enhance management practices and performance of BioPort, our anthrax vaccine supplier.

Second, we have identified and are contracting with a second source for testing, filling and packaging of the vaccine.

Third, on June 30, 2000, the Department issued, through the Commerce Business Daily, a “sources sought” announcement seeking to identify interest in the industry in providing a second source for the manufacture of anthrax vaccine. This is to explore the feasibility of another producer that would share the product license with the BioPort Corporation, but provide a second manufacturing capability. Responses are due July 31st, with the possibility of contract award following as soon as submissions received can be appropriately reviewed.

Fourth, late this month I will be chairing the Defense Resources Board that will make a decision on whether or not to request funds to build a Government-Owned, Contractor-Operated facility to manufacture a variety of vaccines to address the most likely and deadly spectrum of threats to our Soldiers, Sailors, Airmen, Marines, and Coast Guardsmen.

This budget may also include funds to continue development of recombinant vaccines designed to provide protection against multiple threats. One of these will likely be anthrax and serves as our long-range strategy to provide our troops the protection they will need from this deadly agent.

Fifth, we are restricting further payments to BioPort to only those items requested by DoD and allowable as expense costs to comply with both good government fiscal practices and Congressional direction.

Lastly, the Secretary has directed Admiral Jarrett Clinton of the Public Health Service, our First Assistant to the Assistant Secretary of Defense for Health Affairs, and Dr. Hans Mark, Director of Defense Research and Engineering, to contract with a private organization to provide an independent review of the Department's management of vaccine procurement. This will further ensure that our efforts are credible, consistent and cost effective.

WHY TAKEN

We have reached a point with existing stocks of previously manufactured vaccine where there does not appear to be sufficient usable lots of vaccine eligible for release. There are a few lots of vaccine which have met sterility, purity and safety standards but still need to pass a potency test to be considered by FDA for release. We will continue our efforts working with the manufacturer and the FDA to gain approved release of these lots of existing stocks. In connection with this effort, we are also focusing on validation of the potency test the FDA uses to carefully assess the manufacturer's test data to determine if they have met criteria for lot release. Additional vaccine lot release would greatly facilitate our ability to continue vaccination protocols until newly produced vaccine is available.

At this time, re-licensure of newly produced vaccine by our manufacturer is the focus of a very concentrated effort. BioPort purchased the license and the State-owned facility from the state of Michigan in 1998. They have not yet been able to meet the planned licensure and production schedule and still await final approval of their newly renovated facility. There are many reasons for these delays, some within and some beyond BioPort's control. Some are simply related to the inherently complex process of producing biological products. Some are the result of the evolving nature of good manufacturing practices that are required of a modernized manufacturing facility. Some are challenges also being encountered by others in the vaccine industry.

As a consequence, we must now re-focus our program because the available supply of vaccine in which we can place full confidence is insufficient to continue the program at its present pace. Working with the Commanders-in-Chief of the High Threat Areas, we will continue to provide protection to our troops at highest risk. We will accomplish this process consistent with FDA regulations and direction, maintaining our strong focus on safety and protection for our troops.

THE GROWING THREAT

The well-documented and highly lethal biological-warfare threat has been presented to you previously. This threat is real. Several countries either have or are attempting to acquire anthrax as a biological weapon. Many of our military men and women, stationed around the world, go to work each day under the threat of a weaponized, aerosolized anthrax attack. This very difficult to detect

agent is one of the few biological warfare weapons that are almost always fatal in unprotected persons. Protecting those of our members most at risk of exposure is, therefore, our highest priority.

Since inception of the Anthrax Vaccine Immunization Program, the Department has provided many Service Members the best around-the-clock protection available—vaccination using an FDA-licensed safe and effective vaccine. Since we last appeared before you, safety and efficacy has been reviewed and revalidated, dosing timeliness has improved, refusals have decreased in rate and some previous refusers have changed their minds and returned to active duty.

CONCLUSION

The threat is both real and now. More than 455,000 servicemen and women have received over 1.8 million shots and today are benefiting from this protection. This is many more than the number protected when our nation was last involved in hostilities. We will be eager to expand vaccinations to include the total force as soon as adequate supplies of safe and effective vaccine are available. We will work fervently with FDA to initiate new production as soon as safely practical and to ensure that the new vaccine fully meets the requirements of safety, purity, sterility and potency.

Our highest priority has always been and will always remain to protect those men and women in uniform who protect America.