Department of Defense Transition Book

Office of the Senior Advisor to the Deputy Secretary of Defense for Chemical and Biological Protection

22 December 2000

Tal le of Co ıter ts

Appendices

I. ORGANIZA TION AN D MANA GEMEN T

A. Organiza tion

1. Miss on Statem ent

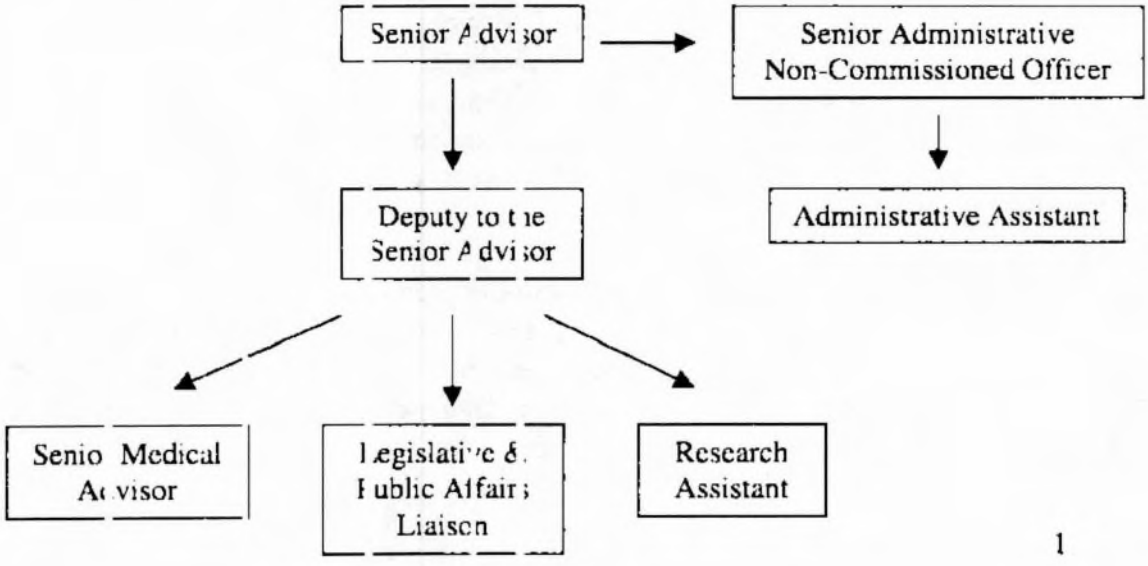
In to lay's era, t he Depart nent of Defe nse faces the serious and ever present chall nge of co ntering th e emerg ng hreat of chemical and biological warfare. The Mission of the Office of the Senio r Advisor to the Deputy Secretary of Defe ise for Che mical and Biologi al Protection is predominantly to advise the Dep ty Secretary of Defe ise on polic es concerning the protection of U.S. milit ry forces a gainst the threats of c emical and biological warfare. In this proc ss, the Off ce monit rs and a ses ses the Department's programs and policies deve oped to pr tect U.S. military for es against the threats of chemical and biolc gical warfa re and he ps to en ure consistency in the Department's polices conc rning biol gical and chemic l pr tection.

2. Orga ization St ucture

The Office of the Senior Advisor on Chemical and Biological Protection consists of si personnel:

Senio r Advisor
Dep ty to the S nior Adv sor
Senio r Medical Advisor
Legi lative & P blic Affa rs Liaison
Rese rch Assist nt
Senio r Adminis rative No n-Commissi ned Officer
Adm nistrative Assistant

With the follow ng organi zational stru cture:



3. Goals

The goals of the Office of the Senior Advisor to the Deputy Secretary of Defense for Chemical and Biological Protection are to:

Manage the public affairs effort associated with the Anthrax Vaccine Immunization Program (AVIP) in order to ensure an accurate presentation of facts to all the program's audiences.

Monitor the education program provided to all members and their families prior to, during and after the inoculation series commences. Included in these efforts are educational tools such as the AVIP agency web-site, silent training aids, audio visual aids and briefings that are continually updated and improved.

Provide legislators with accurate program information, answering member concerns and inquiries and ensuring balanced information is presented to those members when program opponents misrepresent the facts.

Ensure that a safe and efficacious FDA-released supply stockpile is reestablished as soon as possible, permitting the reinstitution of Phase I followed by an expeditious commencement of Phases 2 and 3.

Promote and ensure the use of the most innovative technology to ensure a better vaccine protocol, route of administration, and an improved medical technology that would provide protection in a less invasive manner.

4. Function

The Deputy Secretary sees a means to achieve a single, consistent, effective program for protecting U.S. forces against the increasing threat of chemical and biological weapons.

The main functions of the Office of the Senior Advisor to the Deputy Secretary of Defense for Chemical and Biological Protection is to maintain involvement in all programs initiated to protect U.S. military forces from the threats of chemical and biological warfare, with particular emphasis on the anthrax threat and to advise the Deputy Secretary of Defense on policy and program aspects of DoD's chemical and biological defense programs (medical and non-medical).

The Office of the Senior Advisor promotes coordination, cooperation, and mutual understanding of chemical and biological defense within the Department of Defense and other Federal agencies. As appropriate, the Senior Advisor consults with the Under Secretaries of Defense for Acquisition, Technology and Logistics;

for Policy; and for Personnel and Readiness; the Secretaries of the Services; the Chairman of the Joint Chiefs of Staff; the Special Assistant to the Secretaries of the Defense for Gulf War Illnesses, Military Readiness, and Military Deployments; and the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense.

In coordination with the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense [DATSD(CBD)], see below, the Senior Advisor serves on boards, committees, and other groups concerned with chemical and biological defense and chemical and biological medical defense.

The Office of the Senior Advisor addresses congressional inquires and public concerns in regard to chemical and biological protection issues.

The Office of the Senior Advisor performs the duties previously performed by the Special Advisor for Anthrax and Biological Defense Affairs to the Under Secretary of Defense (Personnel and Readiness).

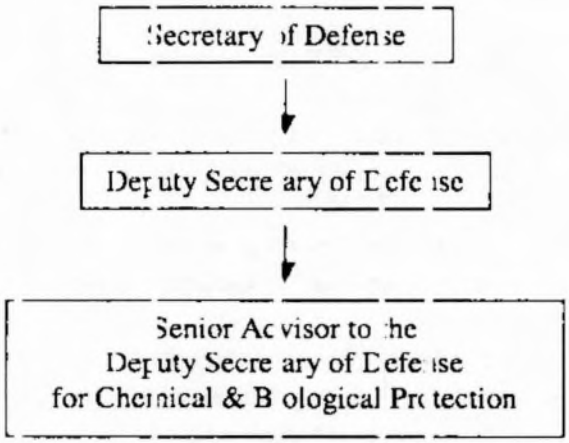
The Senior Advisor acts as one representative for the Deputy Secretary of Defense on these matters outside the Department of Defense.

Perform other functions as the Deputy Secretary of Defense may assign.

B. Management

1. Chain of Command

The Office's Chain of Command is as follows:



The Office of the Senior Advisor on Chemical and Biological Protection coordinates its activities with the DATSD(CBD).

The DATSD(CBD) is the single office that has been charged by the Secretary of Defense according to Title 50, USC, section 1522(b)(1) with the responsibility for overall coordination and integration of the chemical and biological warfare defense program and the chemical biological medical defense program. The Office of the DATSD(CBD) chairs the OSD Chemical and Biological (CB) Defense Steering Committee which is responsible for ensuring policy, oversight and program execution consistent with the DoD's high concern over CB defense.

2. Regulatory Authority

There is no applicable Regulatory Authority.

3. Management Studies and Issues (Studies that focus on organizational structure or operation)

There are no applicable Management Studies and Issues that focus on organizational structure or operation.

C. External Process

1. Executive-Key Interagency Relationships

The Army, as the DoD Executive Agent for the coordination and integration of Research, Development, Test and Evaluation requirements of the Military Departments for CB warfare defense programs.

The Army Surgeon General as the DoD Executive Agent for medical, biological and chemical defense research.

Centers for Disease Control and Prevention (CDC). The Office assisted in obtaining the Fiscal Year 2000 and 2001 funding for, and is monitoring the progress of, the collaborative CDC-DoD research effort established to optimize the anthrax vaccination regimen and to monitor and improve vaccine health care delivery via the Vaccine Healthcare Center Network.

Food and Drug Administration (FDA) The Office meets regularly with the FDA to address the anthrax vaccine supply issue and to monitor the progress of the certification of the newly renovated anthrax vaccine production suite at BioPort Corporation.

2. Congressional

a. Key Committees:

House Government Reform Committee
House Subcommittee on National Security, Veterans' Affairs and International Relations
Senate Armed Services Committee
House Armed Services Committee

b. Critical Reports to Congress:

NUMBER	SECTION	NAME	SYNOPSIS	REPORT DATE
H.R. 3424	SEC 221	Study of Vaccines for Biological Agents	CDC/NIH – Four part study that includes review of anthrax vaccine safety and efficacy and adverse reactions	TBD
H.R. 106-371	TITLE VI	AVIP-NRC Study	Independent safety and effectiveness study	June 2001
		GAO Review of AVIP	AVIP effect on morale, recruiting and retention	Report Pending
H.R. 4205	SEC 751	Management of AVIP	Initiation of procedures to track separations, establish exemptions, notify essential civilian Employees of vaccine requirement	April 2001
		GAO Review of AVIP	AVIP effect on morale, recruiting and retention	April 2002

CDC – Centers for Disease Control; NIH – National Institutes of Health
AVIP – Anthrax Vaccine Immunization Program; NRC – National Research Council;
GAO – Government Accounting Office; TBD – To Be Determined

c. Pending Legislative Issues

- AVIP effect on morale, recruiting and retention of service members
- Use of a sole source contractor BioPort, for the vaccine
- Initiation of a Government Owned-Contractor Operated biological defense vaccine manufacturing facility
- Slowdown Policies
- Exemption Policies (Administrative and Medical)
- Tracking of Number of members who refuse the vaccine and are separated from the military.

II. PERSONNEL

A. Summary of Statistics

Number of personnel in Office
Number civilian personnel
Number military

B. Personnel Management Issues

None

III. POLICY/ISSUES

A. Overview of the Policy Development Process

Draft policy is developed in the Office of the Senior Advisor. The draft policy is then coordinated with other Offices as appropriate, such as Legislative Affairs, General Council, Health Affairs, Personnel and Readiness, Anthrax Vaccine Immunization Program Agency. After coordination is completed, the policy is forwarded to the Deputy Secretary for Defense for review and approval.

B. Major Policy Issues (Requiring attention in next few months)

- Updating of the Total Force Personnel Policy for Administrative Exemptions from the Anthrax Vaccination Immunization Program

- Updating of the Policy on Adherence to the Anthrax Vaccine Immunization Schedule and Medical Exemptions to Anthrax Vaccination

- Resumption of the full-scale AVIP program when the supply of safe and effective FDA approved anthrax vaccine is restored. (The supply of the vaccine will be restored after FDA approves the newly renovated anthrax vaccine production suites; also being considered is the establishment of more than one anthrax vaccine production facility.)

- Movement toward the establishment of a Government Owned, Contractor Operated vaccine production facility to produce vaccines for DoD

- Tracking of anthrax vaccine refusals in military services.

Appendix 1

Transition Issue Paper
Anthrax Vaccine Immunization Program

Statement of Issue: Anthrax is a deadly biological agent that represents a real and highly lethal danger to U.S. service personnel. Secretary Cohen approved the AVIP's implementation in 1998 on the advice and recommendation of the Chairman, the Joint Chiefs of Staff and the Commanders-In-Chief in both Korea and the Middle East. Both CINCs have formally requested that all troops deploying to their theatres be vaccinated.

Background: The process of immunizing the force against anthrax started by vaccinating all our forces deploying to the high threat areas of Korea and the Middle East. To date more than 495,000 service members have started their vaccination series and nearly two million vaccinations have been given. Eventually, the Total Force of approximately 2.4 million, including more than 1 million members of the National Guard and Reserves, will receive the Food and Drug Administration (FDA)-licensed anthrax vaccine.

Status of Issues:

a. An active opposition group with a prolific website continues to raise and inflame issues regarding the safety of the anthrax vaccine. Some service members have refused to take the vaccination, and concerns have been raised regarding the AVIP's impact on recruiting, retention and morale.

b. Delays in obtaining FDA approval of the sole anthrax vaccine manufacturer's recently renovated production facility resulted in the Secretary of Defense's decision to implement temporary slowdowns of the AVIP (July and November 2000) until additional FDA-approved vaccine becomes available. Vaccination continues for personnel assigned to the high-threat area of Southwest Asia. Full resumption of the vaccinations will begin when sufficient supply of FDA released vaccine is available.

c. FY 2001 National Defense Authorization Act language requires the program to implement: (1) exemptions, (2) adverse reactions monitoring; (3) emergency essential civilian personnel notification of AVIP requirement; (4) a prohibition against acquisition fund obligation until FDA approval of the BioPort facility; and (5) a report on the Department's strategies for the acquisition of biological warfare vaccines.

Recommended Actions: Continue oversight for the program's overall implementation, particularly in the areas of (1) effectively articulating DoD's commitment to the health and safety of the service men and women; (2) managing the communications and public affairs challenges; (3) identifying and addressing any real impacts of the AVIP on recruiting, retention and readiness; (4) managing stockpile, acquisition, and research and development programs; and (5) implementing Congressional mandates.

Justification: *Near term*: Provides DoD with effective oversight in managing the slowdown, current research and development programs, and re-implementation of the full immunization program as soon as practical. *Long term*: Establishes a quality BW vaccine program, implements a Vaccine Healthcare Network committed to improvements in the DoD model for all vaccine immunization program.

Risk of Action/Inaction: Insufficient Force Protection for our military forces and essential civilian DoD personnel

POC: (b)(6)

Appendix 2

ISSUE PAPER

AN THRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

A. BACKGROUND:

1. Secretary Cohen approved the implementation of the AVIP in 1998 on the advice and recommendation of the Chairman, the Joint Chiefs of Staff and the Commanders-In-Chief in both Korea and the Middle East. Both CINCs formally requested that all troops deploying to their theatres be vaccinated. Since the AVIP's March 1998 inception, more than 495,000 service members have started their vaccination series and nearly two million vaccinations have been given. Eventually, the Total Force of approximately 2.4 million, including more than 1 million members of the National Guard and Reserves will receive the Food and Drug Administration (FDA)-licensed anthrax vaccine.

2. Since implementation, several vaccine acquisition/supply challenges have been encountered including delays in the FDA approval of the recently renovated production facility of the sole manufacturer, BioPort Corp. of Lansing Mich.. Additionally further delays have been caused by problems with reestablishing a consistent testing protocol to recertify existing stocks of vaccine for sterility, surety and potency. These delays have resulted in the Secretary of Defense's decision to implement temporary slowdowns (July and November 2000) until additional FDA-approved vaccine becomes available. These temporary slowdown actions were necessary to conserve available vaccine supply while continuing to protect those service members at greatest risk. Vaccinations continue for personnel assigned to the high-threat area of Southwest Asia. Full resumption of the vaccination effort will begin when sufficient supply of FDA-released vaccine is available. In order to reduce the risk associated with a sole source, DoD is pursuing a second source for the anthrax vaccine.

3. A number of Congressional hearings (SASC, HASC, and HGRC) have focused on the DoD's management of the AVIP, its vaccine procurement strategies, the safety and effectiveness of the vaccine, and readiness and retention issues. These hearings, in part, led to the FY 2001 National Defense Authorization Act language requiring: (1) establishment of policies and procedures for medical and administrative exemptions, (2) an improvement in the system for monitoring adverse reactions; (3) institution of regulations pertaining to notification of required participation in the AVIP by emergency essential civilian personnel; (4) a prohibition against obligating any funds for acquisition of anthrax vaccine until the FDA has approved the BioPort facility; and (5) a report on the Department's strategies for the acquisition of biological warfare vaccines.

4. Construction and operation of a government-owned, contractor-operated (GOCO) vaccine production facility for future critical Biological Defense vaccines is being pursued as another alternative. The GOCO concept offers the ability to overcome potentially limited industry interest and meets a high national security priority for additional Biological Defense vaccine production.

B. DoD POSITION

The threat is real--biological warfare represents a grave and urgent danger to the Armed Forces of the United States. This mandatory program was initiated and continues because it

provides the best protection available to our service members at this time. The anthrax vaccine's safety and efficacy have been proven through numerous studies. The evidence of efficacy of the FDA-licensed anthrax vaccine is based upon data from both human and animal research. Several studies show that the anthrax vaccine, which has been licensed since 1970, is safe, with an incidence of minor, temporary side effects, after injection similar to other common vaccines.

C. QUESTIONS AND ANSWERS.

1. **Question:** Why do you believe the anthrax threat is significant enough to make the Anthrax Vaccine Immunization Program mandatory for all active and reserve service members?

Proposed Response: Today, at least 10 countries including Iraq and North Korea, now have — or are attempting to acquire or produce — deadly chemical and biological weapons, in particular weaponized anthrax. According to the Chairman of the Joint Chiefs of Staff, anthrax is the number one biological threat. For those who inhale anthrax but have not been vaccinated or treated in time, death is the ultimate and predictable outcome. However, with vaccination, many of those deaths could be prevented. Vaccination is a requirement for all service members and must remain so — voluntary participation would result in having only part of our force protected opening the way to uncertainty and unacceptable risk for our people and their mission. When our people go into battle, they need to know that all, and not merely some, of those who serve with them have full protection from weaponized anthrax.

2. **Question:** When do you anticipate running out entirely?

Proposed Response: At the current slowdown rate of consumption, it is anticipated that current supply will last until November 2001.

3. Question: When will sufficient supply of anthrax vaccine be available?

Proposed Response: When the FDA approves and licenses the newly renovated BioPort manufacturing facility and releases newly produced vaccine, sufficient supply will be available.

D. FOR ADDITIONAL INFORMATION.

Author: (b)(6) [redacted]

For further information: Senior Advisor to the Deputy Secretary of Defense on Anthrax and Biological Defense Affairs - MajGen Randy West (b)(6) [redacted]

Date: December 18, 2000

INFORMATION PAPER

ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)

BACKGROUND

- Biological warfare is a growing threat and, at least ten countries, including North Korea and Iraq, are known to have a biological warfare program that either has or is attempting to acquire anthrax as a biological weapon. Anthrax is a deadly biological agent that represents a real and highly lethal danger to U.S. service personnel. This tasteless, odorless, colorless and difficult to detect silent killer is almost certain death for those unprotected personnel exposed to it.

- If an unvaccinated individual inhales aerosolized anthrax, he or she has little chance of survival. There is an available antibiotic, but it must be taken before symptoms develop. Since aerosolized anthrax is very difficult to detect, exposure will frequently not be apparent until after symptoms develop. We have protective clothing and equipment but it is heavy, bulky and difficult to fight in, especially when it is worn for long periods of time. We have some state of the art detectors, but they do not possess the required sensitivity to be considered reliable.

- Vaccination is the safest, most reliable way to protect our service members from this threat. If a vaccinated individual inhales aerosolized anthrax, he or she will likely survive the exposure unaffected. The anthrax vaccine is safer than most vaccines, including those routinely given to children and has an excellent safety record since first licensed and approved by the Food and Drug Administration (FDA) in 1970. This safety is supported by publications in the medical community including an article in the December 1999 issue of the Journal of the American Medical Association. In the face of the growing anthrax threat and with the availability of a safe and effective anthrax vaccine, DoD has felt morally obligated to provide that protection to its personnel.

- Secretary Cohen approved the implementation of the AVIP in 1998 after an extensive two-year review and on the advice and recommendation of the Chairman, the Joint Chiefs of Staff and the Commanders-In-Chief in both Korea and the Middle East who have formally requested that all troops deploying to their theaters be vaccinated.

- Before final approval was given, Secretary Cohen stipulated stringent supplemental testing of the vaccine stockpile for potency, purity, sterility and general safety, and directed an independent evaluation by the former Dean of the Yale University Medical School.

- We started the process of immunizing our force against anthrax by vaccinating all our forces deploying to the high threat areas of Korea and the Middle East. To date more than 495,000 service members have started their vaccinations and nearly two million vaccinations have been given since the AVIP began vaccinations in March 1998. Eventually, the Total Force of approximately 2.4 million, including more than 1 million members of the National Guard and Reserves, will receive the FDA-licensed anthrax vaccine.

ISSUES

- Initially, the program was presented to members via command briefings and educational materials. It soon became apparent that several Internet sites were presenting information contrary to then-current educational tools. Concerns about the safety of the anthrax vaccine, and small numbers of service members who refused to take the vaccination raised public concerns regarding the AVIP's impact on recruiting retention and morale. The Department has responded by providing several improved educational tools, including an improved anthrax website and refined educational materials to address service member and public concerns. Another challenge - related to DoD's vaccine acquisition program include delays in the sole contractor obtaining FDA approval of its recently renovated production facility.

- These delays caused the Secretary of Defense to implement temporary slowdowns of the AVIP (July and November 2000) until additional FDA-approved vaccine becomes available. Vaccination continues for personnel assigned to the high-threat area of Southwest Asia. These slowdowns were necessary to conserve available vaccine supply while protecting those service members at greatest risk. Full resumption of the vaccination effort will begin when sufficient supply of FDA-approved and certified safe and effective vaccine is available.

CONGRESSIONAL INTEREST

- A number of Congressional hearings (SASC, HASC, and HGRC) have focused on DoD's management of the AVIP, vaccine procurement strategies, the safety and effectiveness of the vaccine, and readiness and retention issues. These hearings, in part, led to FY 2001 National Defense Authorization Act language requiring: (1) procedures for medical and administrative exemptions, (2) a system for monitoring adverse reactions; (3) regulations pertaining to notification of required participation in the AVIP by emergency essential civilian personnel; (4) a prohibition against obligating any funds for acquisition of Anthrax vaccine until the FDA has approved the BioPort facility; and (5) a report on the Department's strategies for the acquisition of biological warfare vaccines.

- While Members of Congress routinely inquire about the AVIP on behalf of constituents, the most notable congressional scrutiny has come from the House Government Reform Committee. Although the Department can expect hearings from the SASC and HASC on NDAA–related AVIP issues, the HGRC, and its subcommittee on National Security will likely continue confrontational hearings on the morale, readiness and health impacts of the AVIP

- Prominent HGRC critics include Rep Dan Burton (R-Ind.), Chairman of the House Committee on Government Reform and Rep. Christopher Shays (R-Conn.), Chairman of the House Government Reform Subcommittee on National Security, Veterans' Affairs, and International Relations. More than any other members, these two Congressmen have sponsored strident oversight and investigational hearings on these matters In particular, Rep. Christopher Shays' subcommittee issued a report questioning both the safety and effectiveness of the vaccine, recommending that DoD designate the vaccine as experimental, and suspend mandatory immunizations until an improved vaccine is available.

PROJECTED EVENTS

Implement Congressional mandates
Manage communications and public affairs challenges
Transition from Slowdown status back to full implementation program
Implement Vaccine Health Care Network
Monitor Centers for Disease Control studies

BUDGET AND PROGRAM DATA: ($ in millions)

	FY00	FY0	FY02-07	Total
Research & Development	20	24	120	164

Establishment (f the Offic e of the S nior Ad visc r to the Deputy Secretary of Defense for Chemical and Bio ogi al Protection

The Office of th e Senior A lvisor for Chemic l a d Biological Defense Protection in the Office of the De puty Secre ary of De fense wa s in stituted in June 2000.

The Office was nitially est ablished *a d hoc* in Au gust 1999 by the Under Secretary of Defense for Per onnel and Readiness under th e C ffice of the Under Secretary of Defense for Personnel ar d Readines s. It was stablish ed t o address the congressional and public concerns and qu eries regar ling the a thrax vacci ation program. At that time the office was entitled, Of ice of the Special Ac visor to the Under Secretary of Defense (Personnel and Readiness) or Anthrax and Biol gical De fen se.

Since its incepti on, the Office has ma naged se ver l vaccine related activities including: advising the De uty Secret ry of Def nse on nar aging the implementation of two vaccination slow downs; pr eparing fo r and pa tici pating in eight congressional hearings; initiating and m nitoring the implem ntation of n edical and administrative policies; and leading efforts t secure $3 5 million n researc h f nding for the Centers for Disease Control and Pre ention to study and m ake imp ro ements to several aspects of the vaccine program. In add ition, the C ffice tem orarily ssi ned personnel to BioPort Corporation in Lansing, MI, o provide technical s upport to su plement the manufacturer's efforts to secure FDA app oval of stockpiled v ccine. The Office has also initiated efforts to establish a Vacc ne Healthcare Cente network to improve the quality of vaccine health care delivery.

The Office has b en transfe red from the Offi e o the Under Secretary of Defense for Personnel and R adiness to the Offic of the Dep ty Secretary of Defense in order to monitor this vita aspect of our Force Protecti n a the highest levels and convey senior leadership intere st in this vi al protect on prog am

There is continu d congress ional and public in ter st in the anthrax vaccine issues, and it is expected that t he Office c f the Seni or Advis or f or Chemical and Biological Defense Protection will b e required or at leas t an addition l 6-12 months.