CMAT Control #
2003006-0000017

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

January 3, 2003 2:45 PM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Representative Oxley's Inquiry for Information on the Anthrax Vaccine Immunization Program

- Representative Oxley requested we provide a response to one of his constituents, Ms (b)(6) regarding the Anthrax Vaccine Immunization Program. As a concerned citizen, Ms. (b)(6) has numerous concerns regarding our servicemembers and the anthrax vaccine immunization program.

- The proposed response explains AVIP policy that addresses her concerns.

RECOMMENDATION: Sign letter at TAB A.

COORDINATION: TAB C

Prepared by: COL (b)(6) AVIP Office, PCDOCS # 44427 R/44440

HA/TMA Document Profile

44427

Subject: AVIP Problem

Author: Oxley, Michael MOC
Date of Document: 10/25/2002
OSD # :
PR # :
Organization:
Department:
Assigned To: DHS
Prepared For: ASD
Suspense Date: 1/7/2003
Coord Office(s):

Congressional Name: Oxley, Michael MOC
Input By: VESPINAL
Profiler's Directorate: Admin, HA
Response Signed By:
Dt Response Signed:
Doc Type: MEMO
Application: DOCSIMAGE
Previous Documents:
Related Documents:

Notes: SHORT SUSP. Tasked by LTC (b)(6)

Beneficiary Info

Beneficiary Name: (b)(6)
Address 1:
Apartment #
Phone #
Email Address:
City: (b)(6)
State: **Zip:** (b)(6)

History

Created: 1/3/2003 HA PCDOCS Adr
Edited: 1/3/2003 HA PCDOCS Adr
Status: Available

Retention Schedule

Type: Archive
Retention Days: 365

☐ From External Source?

Access Control

☒ Secure Document
☐ Enable Content Searching

DEC 10 2002 4 48PM NO 6863 P 1 2

MICHAEL G OXLEY
COMMITTEE ON FINANCIAL SERVICES

Congress of the United States
House of Representatives
Washington, DC 20515-3501

Faxed from the Office of
Congressman Michael G. Oxley
Fourth Ohio District

To: Dr. William Winkenwerder

From: ☐ Michael G Oxley ☐ Tim Johnson ☐ Dirk Bartlett
☐ Jim Conzelman ☒ Peter Erdman ☐ Jen Mundy
☐ Debi Deimling ☐ Jared Dilley ☐ _____

Date 12 / 10 / 2002 Pages (including cover): 2

Subject: AVIP problem

Comments:

Any help in response to this constituent's concern would be appreciated.

Thanks

[redacted]

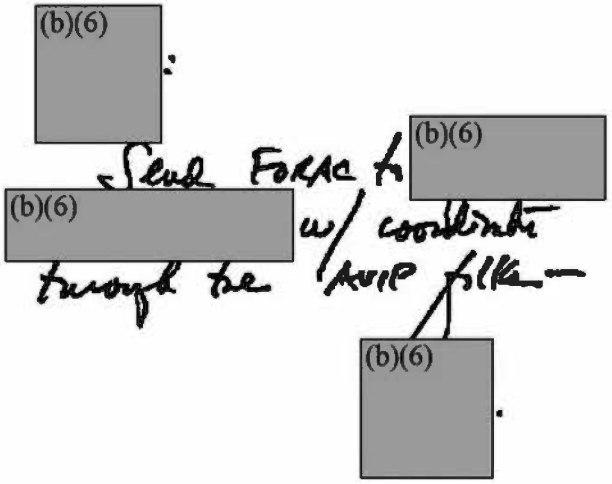
From: writerep
Sent: Friday, October 25, 2002 1:12 PM
To: OH04WYR
Subject: WriteRep Responses

DATE October 25, 2002 12 51 AM
NAME. (b)(6)
ADDR1
ADDR2.
ADDR3
CITY
STATE
ZIP:
PHONE:
EMAIL.
msg:
Dear Congressman Oxley,

I am writing as a concerned citizen I am urging you to investigate and help stop the mandatory Anthrax Vaccine Immunization Program (AVIP) of our service men and women. Anthrax vaccine is unsafe, untested, unnecessary, unpopular, unethical, and not totally effective. Early symptoms following the first or second shot that have been reported in high numbers include headaches, malaise, respiratory distress, chills, diarrhea, fever, and abdominal cramping. Later chronic symptoms reported often after the third or fourth shot have included dizziness, chronic fatigue, chest pains, sleep disorders, memory loss, headaches, joint and muscle pain, peripheral sensory neuropathies, recurring rashes, blackouts, autoimmune diseases, swelling of limbs, collagen vascular disease, sepsis, cardiomyopathy, nausea, night sweats, cysts, tunnel vision, and seizures This information can be found at the CDC website www cdc gov/mmwr/preview/mmwrhtml/rr4915a1.htm and in the book "Anthrax A Deadly Shot In The Dark" by Thomas S Haemstra Six people have died following anthrax immunization. Our service men and women make great sacrifices of time and sometimes their lives to defend our great nation, but they should not have to sacrifice their health because of this unsafe vaccine or risk court-martial if they refuse it Civilians are given a choice concerning this vaccine and so should our service men and women be given that same choice. Further research needs to be done to find a safe and effective anthrax vaccine

Sincerely,
[redacted]

DOD Leg Affairs
(b)(6)
(b)(6)
(b)(6)
fax
(b)(6)
Dr. W. Kornblith


(b)(6)
(b)(6)
(b)(6)
(b)(6)

(b)(6) **LTC, OASD(HA)**

From: (b)(6) COL OTSG (b)(6)
Sent: Wednesday, December 25, 2002 5 47 PM
To: (b)(6)
Subject: Draft Letter for ASD(HA) Signature
Importance: High

(b)(6) **As requested.**

-----Original Message-----
From: (b)(6)
Sent: Tuesday, December 24, 2002 1:35 PM
To: (b)(6) COL OTSG
Cc: LTC OTSG
Subject: Letter

(b)(6)

Attached is the final version of the letter

(b)(6)

Executive Office

(b)(6)

Dear Ms (b)(6)

Thank you for your recent e-mail concerning the Anthrax Vaccine Immunization Program (AVIP) I share your concern for our service members Preserving their health and safety is our #1 concern The Department of Defense (DoD) requires anthrax vaccination for certain service members as an added layer of protection against this potentially deadly biological agent

The threat of biological warfare has been a risk to U S forces for many years DoD analysts maintain updated threat-level evaluations, adjusting the information as necessary to reflect the risk to U S operations Based on assessment of current and past activities in such areas as Iraq and the former Soviet Union, the potential offensive biological threat facing service members makes it necessary for the DoD to have a robust biological-defense program today Anthrax is one of the deadliest biological weapons of choice

As with other vaccines, the benefits of the U S Food and Drug Administration (FDA)-licensed anthrax vaccine far outweigh any risk The Centers for Disease Control and Prevention (CDC) states that getting vaccinated is much safer than getting the diseases the vaccines prevent Such biological agents as anthrax are especially hard to detect Symptoms are delayed, and without preventive medical efforts, such as vaccination, the results can be devastating and widespread

Medical experts agree there have been no deaths found to be caused by anthrax vaccine reported among more than 2 2 million immunizations given to over 567,000 service men and women since the Anthrax Vaccine Immunization Program began in March 1998 Further, no deaths have been attributed in a cause-and-effect manner to the vaccine since the FDA licensed it over 30 years ago

Many studies establish anthrax vaccine safety From a 1958 study published in the *Bulletin of the Johns Hopkins Hospital,* to more recent studies at Fort Detrick, Maryland, evidence shows that there are no known long-term side effects to the anthrax vaccine In 2002, the National Academy of Sciences Institute of Medicine's Committee to Assess the Safety and Efficacy of the Anthrax Vaccine concluded their two-year study In their published findings, the Committee found "no evidence that people face an increased risk of experiencing life-threatening or permanently disabling adverse events immediately after receiving AVA, when compared with the general population

"Nor did it find any convincing evidence that people face elevated risk of developing adverse health effects over the longer term, although data are limited in this regard (as they are for all vaccines) "*

The IOM Committee studied data on anthrax-vaccine effectiveness and concluded "that the available evidence from studies with humans and animals, coupled with reasonable assumptions of analogy, show that AVA as licensed is an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by any known or plausible engineered strains of *B anthracis* "*

The DoD continually strives for improved vaccines and improved vaccination programs to protect the health of our force The DoD is currently collaborating with the CDC in their study to determine different ways to administer the current anthrax vaccine This study may lead to the FDA's allowing its use in fewer doses and administering it in a way that may reduce bothersome local injection-site redness, pain, swelling and itching Additionally, the DoD is partnering with the Department of Health and Human Services to develop a "next generation" anthrax vaccine, which may be as effective and safe as the current vaccine in fewer doses Both these efforts are important, but will take years to conclude Meanwhile, we must protect our service members from harm with the currently licensed, safe and effective vaccine

I trust this information addresses your concerns and I invite you to visit the AVIP's Internet Web site at http //www anthrax mil, or call the toll-free information line at 1-877-GET-VACC for more in-depth information about the anthrax-vaccine program Answers to other questions are also available by writing to avip@otsg amedd army mil

*Source "The Anthrax Vaccine Is It Safe? Does It Work?" Published in 2002 by the National Academy Press, www nap edu/catalog/10310 html

(b)(6) **LTC, OASD(HA)**

From: (b)(6) LTC, OASD(HA)
Sent: Friday, December 27, 2002 11 17 AM
To: CON, OASD(HA)/TMA
Subject: RE Draft Letter for ASD(HA) Signature

Tracking:

Recipient	Read
CON, OASD(HA)/TMA	Read 12/27/2002 11 24 AM

Would your shop be able to put the coordination package together? It should be assigned to FHP & R and prepared for Dr Winkenwerder's signature

If I should be doing something differently, please let me know

(b)(6)

-----Original Message-----
From: (b)(6) CON, OASD(HA)/TMA
Sent: Friday, December 27, 2002 10:58 AM
To: (b)(6) LTC, OASD(HA)
Subject: RE Draft Letter for ASD(HA) Signature

I can't find it in PCDOCS Have not seen it up here

-----Original Message-----
From: (b)(6) LTC, OASD(HA)
Sent: Friday, December 27, 2002 10:39 AM
To: (b)(6) CON, OASD(HA)/TMA
Subject: FW: Draft Letter for ASD(HA) Signature
Importance: High

(b)(6)

Is this response in PCDOCS? I have been unable to find it

(b)(6)

-----Original Message-----
From: (b)(6) COL OTSG [mailto
Sent: Wednesday, December 25, 2002 5:47 PM
To: (b)(6)
Subject: Draft Letter for ASD(HA) Signature
Importance: High

(b)(6) **As requested. GMR**

-----Original Message-----
From: (b)(6)
Sent: Tuesday, December 24, 2002 1 35 PM
To: (b)(6) COL OTSG
Cc: LTC OTSG
Subject: Letter

(b)(6)

Attached is the final version of the [redacted] letter

(b)(6)

1/3/2003

[redacted] CIV, OASD(HA)/TMA [redacted] on 01/03/2003 10:24:44 AM

Pc Doc's 44427

To: (b)(6) DHSD (b)(6)
cc:

Subject: Hot suspense

(b)(6)

We will be sending you a hot suspense that we received from LTC (b)(6) suspense date will be 1/7/03. Please work asap.

(b)(6)
Staff Assistant
Document Management Division
(b)(6) fax
(b)(6)

[redacted]

[redacted]

[redacted] (b)(6) [redacted]

[redacted] (b)(6) [redacted]

[redacted] COL OTSG" [redacted]
on 01/04/2003 04:39:02 PM

To: (b)(6)
cc:

Subject: FW: REP OXLEY RESPONSE TO MS. HAUSHALTER

(b)(6)

Attached are 3 recommended (well, corrects mistakes, so important to "accept") changes using Word's Tracking Tool. I don't intend to be mean or snippy here, but these were correct in the draft I sent originally. I realize you folks made some editorial changes to express differently than me in a couple places, and I appreciate that license; however, pls don't make changes that are mistakes.

Thanks, (b)(6)

-----Original Message-----
From: (b)(6)
[mailto:(b)(6)
Sent: Friday, January 03, 2003 1:24 PM
To: (b)(6)
Cc:
Subject: REP OXLEY RESPONSE TO MS. HAUSHALTER
Importance: High

(b)(6)

Attached is the proposed response to Ms. [redacted] regarding AVIP. If you both concur and respond via email, I will send this forward for Ms. [redacted] coordination and ASD(HA) signature.

(See attached file: Rep Oxley - AVIP Problem 1-3-03.doc)

- Rep Oxley - AVIP Problem 1-3-03.doc

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

(b)(6)

Dear Ms. (b)(6)

Thank you for your recent e-mail concerning the Anthrax Vaccine Immunization Program (AVIP). I share your concern for our servicemembers. Preserving their health and safety is our number one concern. The Department of Defense (DoD) requires anthrax vaccination for certain servicemembers as an added layer of protection against this potentially deadly biological agent.

The threat of biological warfare has been a risk to U.S. forces for many years. DoD analysts maintain updated threat-level evaluations, adjusting the information as necessary to reflect the risk to U.S. operations. Based on assessment of current and past activities in such areas as Iraq and the former Soviet Union, the potential offensive biological threat facing servicemembers makes it necessary for the DoD to have a robust biological defense program today. Anthrax is one of the deadliest biological weapons of choice.

As with other vaccines, the benefits of the U.S. Food and Drug Administration (FDA) licensed anthrax vaccine far outweigh any risk. The Centers for Disease Control and Prevention (CDC) states that getting vaccinated is much safer than getting the diseases the vaccines prevent. Biological agents such as anthrax are especially hard to detect. Symptoms are delayed, and without preventive medical efforts such as vaccination, the results can be devastating and widespread.

Medical experts agree, there have been no deaths from anthrax vaccine reported among more than 2.2 million immunizations given to over 567,000 servicemen and women since the Anthrax Vaccine Immunization Program began in March 1998. Further, no deaths have been attributed in a cause-and-effect manner to the vaccine since the FDA licensed it over 30 years ago.

Many studies establish anthrax vaccine safety. From a 1958 study published in the *Bulletin of the John Hopkins Hospital*, to more recent studies at Fort Detrick, Maryland, evidence shows that there are no long-term side effects to the anthrax vaccine. In 2002, the National Academy of Sciences, Institute of Medicine's (IOM) Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, concluded their two-year study. In their published findings, the Committee found "no evidence that people face an increased risk of experiencing life-threatening or permanently disabling adverse events immediately after receiving AVA, when compared with the general population.

"Nor did it find any convincing evidence that people face elevated risk of developing adverse health effects over the long term, although data are limited in this regard (as they are for all vaccines)."*

The IOM Committee studied data on anthrax-vaccine effectiveness and concluded "that the available evidence from studies with humans and animals, coupled with reasonable assumptions of analogy, show that AVA as licensed is an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by any known plausible engineered strains of B anthracis." *

The DoD continually strives for improved vaccines and improved vaccination programs to protect the health of our forces. The DoD is currently collaborating with the CDC in their study to determine different ways to administer the current anthrax vaccine. This study may lead to the FDA's allowing its use in fewer doses and administering it in a way that may reduce bothersome local injection-site redness, pain, swelling and itching. Additionally, the DoD is partnering with the Department of Health and Human Services to develop a "next generation" anthrax vaccine, which may be as effective and safe as the current vaccine in fewer doses. Both of these efforts are important, but will take years to conclude. Meanwhile, we must protect our servicemembers from harm with the currently licensed, safe and effective vaccine.

I trust this information addresses your concerns and I invite you to visit the AVIP's Internet Website at http://www.anthrax.mil, or call the toll-free information line at 1-877-GET-VACC for more in-depth information about the anthrax-vaccine program. Answers to other questions are also available by writing to avip@otsg.amedd.army.mil.

Sincerely,

William Winkenwerder Jr., MD

Cc:
The Honorable Michael G. Oxley

* Source - "The Anthrax Vaccine, Is It Safe? Does It Work?" Published in 2002 by the National Academy Press, www.nap.edu/catalog/10310/html.

Friday, January 10, 2003 2:23 PM Profile

CMAT Control # 2003010-0000016

HA/TMA Document Profile

44651

(2)

Subject:	Questions Regarding the Administrations's Smallpox Vaccination Policy		
Author:		**Congressional Name:**	Representative Ron Paul
Date of Document:	12/20/2002	**Input By:**	GSHAPIRO
OSD # :	U00328/03	**Profiler's Directorate:**	
PR # :		**Response Signed By:**	
Organization:		**Dt Response Signed:**	
Department:		**Doc Type:**	102-05
Assigned To:	FHP&R	**Application:**	DOCSIMAGE
Prepared For:	USD(P&R)	**Previous Documents:**	
Suspense Date:	1/15/2003	**Related Documents:**	
Coord Office(s):	LA	**Notes:**	On 1/10/03 DMD/PNT scanned into PCDOCS and assigned to FHP&R.(gjs)

Beneficiary Info

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Apartment #	
Phone #	
Email Address:	
City:	
State:	**Zip:**

History

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Edited: 1/10/2003 HA Red Tag

Status: Available

Retention Schedule

Type: Keep

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SECFILES FULL RECORD DETAIL

Print Date: 1/9/2003

OSD CONTROL U00328-03 DOC 12/20/2002 DOR 1/9/2003 SIGNATURE CASE:
FROM MOC PAUL, R TO SECDEF
SUBJECT QUESTIONS CONCERNING THE ADMINISTRATIONS SMALLPOX VACCINATION POLICY
KEYWORDS SMALLPOX VACCINATION
COMMENTS SA0020721
FN SEC U OCN RDD

STATUS CODE DECISION DECISION DATE PRIORITY ACTION REPORT:
AGENCY UPR ACTION ASSIGNED RDC SUSPENSE 1/15/2003
SUSPENSE COMPLETE ACD COORDINATION LA
SUSPENSE STATUS

INTERIM REPLY INT REPLY TO REPLY IS REPLY TO
REPLY TO 2 CYS RCD PAGES 1 ENCLOSURES

CM FROM CM IS CM DATE CM SC CM COPIES CM PAGES
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CM ENCL ITEM CNT 1 CM CNT LAST ENTRY 01/09/03 14:05 (b)(6)

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Congressional

SECRETARY OF DEFENSE CORRESPONDENCE ROUTING SLIP

Action Agency: **UNDER SECRETARY FOR PERSONNEL & READINESS**
Action Required: **REPLY DIRECT - COMPONENT HEAD MUST SIGN**
Coordinate With: **LA**

Remarks: *SA0020721*

Special Instructions: **FORWARD COPY OF REPLY TO CCD, ROOM 3A948**

Suspense Date: **January/15/2003**	Routing Date: **January/9/2003**	OSD CONTROL #: **U00328-03**

INFORMATION DISTRIBUTION

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GENERAL COUNSEL
EXECUTIVE SECRETARY REAR
C&D

SECRETARY OF DEFENSE CORRESPONDENCE ACTION REPORT

This form must be completed and forwarded to the Correspondence Control Division (CCD), WHS Room 3A948, Suspense Desk: [redacted] FAX Number: [redacted] Email: [redacted]

Action Agency: UPR

Suspense Date: 01/15/2003

1. ACTION TAKEN (Check one)

- [ ] a. ACTION HAS BEEN COMPLETED (Copy attached)
- [ ] b. REQUEST EXTENSION OF SUSPENSE DATE TO [ ] *(Justify below)*
- [ ] c. INTERIM REPLY HAS BEEN SENT (Copy attached) EXTEND SUSPENSE TO [ ] *(Justify below)*
- [ ] d. REQUEST CANCELLATION *(Justify below)*
- [ ] e. REQUEST TRANSFER TO [ ] *(Justify below /include POC Name & Phone Number)*
- [ ] f. REQUEST DOWNGRADE TO [ ] *(Justify below)*

2. JUSTIFICATION

3. REPORTING AGENCY

a. ACTION AGENCY: UPR

b. NAME OF ACTION OFFICER:

c. TELEPHONE NO.:

d. DATE:

e. APPROVING AUTHORITY (Service Secretary/Under Secretary/ASD/Military/Executive Assistant Level)

Signature:

Date Signed:

4. CCD CONTROL

U00328-03

5. ACTION TAKEN (For EXSEC/ Correspondence Control Division Use Only)

a. EXT	[ ] Approved	[ ] Disapproved
b. CANX	[ ] Approved	[ ] Disapproved
c. DWNGRD	[ ] Approved	[ ] Disapproved
d. TRANSFER	[ ] Approved	[ ] Disapproved

e. OTHER (Specify):

Signature:

Date Signed:

SD FORM 391, JAN 2000

RON PAUL
14TH DISTRICT, TEXAS

FINANCIAL SERVICES COMMITTEE
SUBCOMMITTEES
VICE CHAIRMAN
OVERSIGHT AND INVESTIGATIONS
CAPITAL MARKETS, INSURANCE, AND GOVERNMENT-SPONSORED ENTERPRISES
DOMESTIC MONETARY POLICY, TECHNOLOGY, AND ECONOMIC GROWTH

INTERNATIONAL RELATIONS COMMITTEE
SUBCOMMITTEES
INTERNATIONAL OPERATIONS AND HUMAN RIGHTS
WESTERN HEMISPHERE

SECRETARY OF DEFENSE

2002 DEC -5 PM 2:04

Congress of the United States
House of Representatives
Washington, DC 20515–4314

December 20, 2002

203 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2831

312 SOUTH MAIN
SUITE 229
VICTORIA, TX 77901
(361) 576-1231

200 WEST 2ND STREET
SUITE 210
FREEPORT, TX 77541
(979) 230-0009

Secretary of Defense

SA0020721

The Honorable Donald H. Rumsfeld
Secretary of Defense
Department of Defense
1000 Defense Pentagon
Room 3E 880
Washington, DC 20301

Dear Honorable Rumsfeld:

Please provide answers to the following questions regarding the administration's smallpox vaccination policy:

1. What repercussions will be faced by members of the military who refuse the smallpox vaccine?

2. What remedies are available to military personnel who experience negative reactions to the smallpox vaccine?

Please contact Mr. [redacted] my legislative director, if you have any questions regarding this request. Thank you in advance for your prompt response to this inquiry.

Sincerely,

Ron Paul

Ron Paul

U00328 /03

01/10/03 14:59 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1387
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	
ST. TIME	01/10 14:59
USAGE T	00'35
PGS. SENT	2
RESULT	OK

Deployment Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
(b)(6)
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET

TO: (b)(6) **FROM:** EDR (b)(6)

ORGANIZATION: MILVAX

FAX NUMBER: [redacted] **TOTAL NO. OF PAGES INCLUDING COVER:** 07 02

PHONE NUMBER: **SENDER'S PHONE NUMBER:** [redacted]

SUBJECT

☐ URGENT ☐ FOR REVIEW ☐ PLEASE
☐ COMMENT ☒ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Thanx (b)(6) — Appreciate ANY assistance rendered. IF possible can we get a QUICK RETURN on

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL AND READINESS)

FROM: William Winkenwerder Jr., Assistant Secretary of Defense (Health Affairs)

SUBJECT: Response to Representative Ron Paul Regarding Smallpox Vaccination Policy

- Attached at TAB A is a draft response to Congressman Ron Paul's request for information regarding DoD's smallpox vaccination policy. Specifically:
  - What are the repercussions to military members who refuse the immunization?
  - What remedies are available to military members who experience negative reactions to the vaccine?
- The response is consistent with guidance that is provided in the current DoD administrative and clinical policy memorandum signed by Dr. Winkenwerder.

RECOMMENDATION: That USD (PR) sign letter at TAB A.

COORDINATION: TAB C

ATTACHMENTS:
As stated

44651/R 45045

Prepared by: CDR [redacted] DHSD, [redacted] PCDOCS#~~00000~~

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

The Honorable Ron Paul
United States House of Representatives
Washington, DC 20515

Dear Representative Paul:

I appreciate the opportunity to further elaborate on DoD's Smallpox Immunization program. We are committed to protecting the health and well being of our military forces at all times.

Military personnel at risk of exposure to smallpox are required to take smallpox vaccine to preserve their ability to accomplish their mission. Although some members may be reluctant to receive smallpox vaccine, DoD has made every effort to provide safety efficacy data to educate those individuals on the importance and safety of this vaccine. Prior to smallpox vaccination, members are screened to reduce the risk of side effects. For example, personnel who have certain skin conditions or compromised immune systems are exempted from receiving the vaccine. Those who do receive vaccines usually tolerate them without significant side effects. However, adverse events can occur and may require treatment to relieve symptoms. Personnel are advised to consult a healthcare provider at the nearest medical treatment facility if they believe they are experiencing an adverse event.

Refusals may be regarded as a failure to follow orders. If a member refuses an order, he or she is subject to the standards provided in the Uniform Code of Military Justice. Local commanders have the responsibility to dispose of offenses committed by members of their command and to adjudicate each action only after carefully reviewing and balancing all relevant circumstances to settle those actions at the lowest possible level.

Thank you for your concern for our dedicated men and women of the Armed Forces.

David S.C. Chu

SUBJECT: Response to Representative Ron Paul Regarding Smallpox Vaccination Policy

COORDINATIONS

MILVAX	LTC (b)(6)	Concur 1/15/03
Dir PI, HA	LTC	Concur 1/16/03
DASD, FHP/R	Ms Ellen P. Embrey	Concur 1/17/03
DoD, OGC	Mr. (b)(6)	_____
CoS (HA)	Ms.	_____
PDASD (HA)	Mr.	_____

[redacted]

[redacted] LTC (b)(6) [redacted] (b)(6) [redacted]

[redacted] LTC [redacted]

[redacted] Ms Ellen P. Embrey

[redacted] Ms. (b)(6) [redacted]

[redacted] Ms. [redacted]

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

ACTION MEMO

JAN 2 3 2003

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL AND READINESS)

FROM: William Winkenwerder, Jr., MD, ASD (Health Affairs)

SUBJECT: Response to Representative Ron Paul Regarding Smallpox Vaccination Policy

- Congressman Ron Paul requested information regarding the DoD smallpox vaccination policy. (TAB B)
  - "What repercussions will be faced by members of the military who refuse the smallpox vaccine?"
  - "What remedies are available to military personnel who experience negative reactions to the smallpox vaccine?"
- The response at TAB A is consistent with guidance that is provided in the current DoD administrative and clinical policy memorandums.

RECOMMENDATION: That the USD (P&R) sign at TAB A.

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6) PCDOCS#44651/R45045

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

JAN 2 7 2003

PERSONNEL AND READINESS

The Honorable Ron Paul
United States House of Representatives
Washington, DC 20515

Dear Representative Paul:

I appreciate the opportunity to further elaborate on DoD's Smallpox Vaccination Program. We are committed to protecting the health and well-being of our military forces at all times.

Military personnel at risk of exposure to smallpox are required to take the smallpox vaccine to preserve their ability to accomplish their mission. DoD is conducting a comprehensive campaign to educate our personnel on the importance and safety of this vaccine. Prior to smallpox vaccination, members are screened to reduce the risk of side effects. For example, personnel who have certain skin conditions or compromised immune systems are exempted from receiving the vaccine. Our experience to date has lead to the exemption of approximately 20 percent of eligible members from vaccination. Those who do receive vaccines usually tolerate them without significant side effects. However, adverse events can occur and may require treatment to relieve symptoms. To date, we have had no serious effects. Approximately three percent of service members have had to take a sick day. All have returned to duty. Personnel are advised to consult a healthcare provider at the nearest medical treatment facility if they believe they are experiencing an adverse event. In the very rare, but possible, event of a disabling adverse reaction to the vaccine, the DoD or Department of Veterans Affairs disability benefits programs would provide compensation.

If a military member refuses a lawful order to receive the smallpox vaccine, the member would be subject to possible administrative actions or potential punishment under the Uniform Code of Military Justice, as the member would for refusing to obey any other lawful order. Our program is designed, however, to make every effort to inform members about the vaccine, answer questions and concerns, and promote voluntary compliance. If that fails, a local commander has the responsibility to dispose of alleged offenses by members of his or her command, to carefully review and balance all relevant circumstances, and to assure the member of his or her full rights under the law.

Sincerely,

Charles S. Abell
Principal Deputy

SUBJECT: Response to Representative Ron Paul
Regarding Smallpox Vaccination Policy

CONFIDENTIAL

Mr. (b)(6)

Dr. (b)(6)

23 JAN 03

(b)(6)

SUBJECT: Response to Representative Ron Paul Regarding Smallpox Vaccination Policy

COORDINATIONS

MILVAX	LTC (b)(6)	Concur 1/15/03
Dir PI (HA)	LTC	Concur 1/1 6/03
DASD (FHP&R)	Ms Ellen P. Embrey	Concur 1/17/03
OASD (LA)	Dr. (b)(6)	1/23/03
CoS (HA)	Ms.	
PDASD (HA)	Mr.	

TRICARE

TRICARE Management Activity

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

ACTION OFFICE DHS DATE 1-29-03 PCDOCS # 44651
(b)45045

The attached correspondence is returned for the following reason(s):

- ☑ **Distribution**
- ☐ **Coordination**
- ☐ **Revision**
- ☐ **Correct Signature Block**
- ☐ **Correct Envelope Size**
- ☐ **Correct Letterhead**
- ☐ **Provide Original/Supporting Documents**
- ☐ **Provide SD 391**
- ☑ **Retain for your Files**

(b)(6)

This is done in PcDocs - no mailing necessary - WRS (P;R) mailed. Done in our system & not already done file

(b)(6)

Additional Comments:

Signed Response Scanned into PcDocs # 44651

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE

TRICA RE Management Activity

	Sign	Coord		Sign	Coord
1/23 ASD, HA BW	✓		Dir, TMA		
PDASD, HA					
DASD, C&PP			CMO		
DASD, FHP&R			Dir, DHS		
DASD, HB&FP			CFO		
DASD, HPA			COO		
			Dir, TRICARE Operations/PEO		
CIO, MHS			Dir, IMT&R		
1/23/03 OGC, DoD		✓	OGC, TMA		
1/23/03 LA		✓			
CoS, HA		✓	Dir, A&M		
Military Assistant			CoS, TMA		
Dir, PI, HA			Dir, PI, TMA		
Dir, P&S			Dir, Admin		
Other (Specify)			Other (Specify)		
DMD (SKY) Date:			DMD (PNT) A Date: 1/22/03		

Date Received: 1 22 03 Suspense Date: 1/15/03

Subject: Response to Rep. Ron Paul Regarding Smallpox Vaccination Policy

CDOCS #: 44651, 45045 OSD/P&R #: V00328-03/0104448

TO: CDR [redacted] Office: DHS Phone #: (b)(6)

NOTES: Send comeback copies to PDASD & OLA. → DL A 1/28/0

Orig mailed out by PER Comeback copy to AO. A 1/28/03

~~RTN HA~~

Orig mailed out CCD

Envelope provided copy enclsd

Please call [redacted] for pick up.

(b)(6)

#2003013-00003 12

(3)

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

January 23, 2003, 3:15 PM

FOR: Ellen P. Embrey, DASD, Force Health Protection and Readiness

FROM: COL Terry Rauch, EO, DASD(HA)FHP&R

SUBJECT: Investigational New Drugs (IND) for Force Health Protection

- TAB B is a draft letter to the Commissioner, FDA regarding IND for force health protection.
- TAB C is a letter to the ASD(HA) from the Commissioner, FDA, December 13, 2002.
- TAB D is a letter from the ASD(HA) to the Commission, FDA, November 20, 2002.

RECOMMENDATION: Sign the memo at TAB A.

COORDINATION: TAB E

Prepared by: (b)(6) FHP/R Program Director, Health Science Policy,
(b)(6) PCDOCS# 44537/R 45241

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

JAN 2 8 2003

MEMORANDUM FOR ~~DEPUTY~~ ASSISTANT TO THE SECRETARY OF DEFENSE
(CHEMICAL & BIOLOGICAL DEFENSE)

SUBJECT: Interface with the FDA for Use of Particular IND Products

Dr. Winkenwerder spoke to the Commissioner of the Food and Drug Administration (FDA) and subsequently wrote him a letter on November 20, 2002 (attached). The purpose was to thank the FDA for their efforts since September 11, 2001, to approve drugs and vaccines needed for treatment or prophylaxis of bioterrorism threats and to note that there were several issues that impact our ability for formulate deployment plans for Investigational New Drug (IND) medical products. Specifically, those issues regarding pyridostigmine bromide, botulinum pentavalent toxoid vaccine, and label concerns regarding Anthrax Vaccine Adsorbed (AVA) post exposure with antibiotics and Cidofovir for treatment of smallpox.

The Commissioner of the FDA sent a letter of response dated December 13, 2002 (attached), regarding the use of IND for prophylaxis or treatment to maximize military force health protection capabilities as the war on terrorism and potential new contingencies progress.

Dr. Winkenwerder is sending a response back to the FDA noting that DoD remains eager to work with the FDA to resolve some remaining concerns. Specifically:

a. Pyridostigmine bromide(PB): On January 6, 2003, DoD submitted a New Drug Application (NDA) for PB. Approval of the NDA would eliminate DoD concerns for use of PB under the IND. We await word from FDA Center for Drug Evaluation and Research (CDER) on the approval of the PB NDA.

b. Botulinum pentavalent (BT) toxoid vaccine: We must find a means to provide a limited amount of BT to special units. We are reviewing any other potentially feasible options to address the threat of botulinum toxin. We asked the FDA to continue their stated commitment to work with us to find a resolution to this critically important issue. If this is not a safety issue, can there be a label change or a revision of the informed consent form to allow those who consent to have access to this potentially life saving product?

c. Anthrax vaccine and Cidofovir: FDA replied suggesting that we consider submitting a waiver request with appropriate justification. We agree. We must make such a submission for both of these INDs.

The purpose of this memorandum is to ask you to task the Program Executive Officer for Bio Defense to work with the FDA and USA Medical Research and Materiel Command in an expeditious manner to get approval to use BT in a limited manner for some troops and to provide the required request for waiver for the AVA Post Exposure IND label requirement and the Cidofovir IND label requirement for treatment of smallpox.

My POC is Colonel Terry Resch, who may be reached at (b)(6) email: (b)(6) Thank you in advance for your willingness to see rapid resolution of this matter.

Sincerely,

Ellen Embrey
Deputy Assistant Secretary of Defense
Force Health Protection and Readiness

Attachments:
As stated

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. McClellan:

This is a follow-up to your letter of December 13, 2002, regarding the use of investigational new drugs (INDs) for prophylaxis or treatment to maximize military force health protection capabilities as the war on terrorism and potential new contingencies progress. Thank you and the staff of the Food and Drug Administration (FDA) for your quick response to my letter of November 20, 2002.

DoD remains eager to accelerate approval of several high priority new drug applications which could be required for use in a contingency. Again, first among these is the approval of pyridostigmine bromide as a nerve agent pre-treatment against soman and tabun. Second is the approval of Anthrax Vaccine Absorbed (AVA) as a post-exposure treatment with antibiotics. These continue to be are our high priority concerns.

Unresolved issues remain that currently impact our ability to formulate deployment plans for the following JND medical products in priority order: Pyridostigmine Bromide; Botulinum Pentavalent Toxoid Vaccine; Anthrax vaccine for post-exposure treatment, and Cidofovir as a post exposure treatment for smallpox. Let me discuss the status of these and other issues since your letter. Specifically:

a. Pyridostigmine bromide: An amendedIND protocol was submitted to theFDA on January 6, 2003. This IND protocol included the informed consent language worked out between DoD and HHS/FDA. However, as you know, the execution of an IND protocol during active military operations is highly problematic. Also, on January 6, 2003, DoD submitted a new drug application (NDA) for PB. Approval of the NDA would eliminate DoD concerns for use of PB under the IND, and is extremely important. We await word from FDA on the approval of the PB NDA.

b. Botulinurn pentavalent toxoid vaccine (BT): DoD submitted the additional potency assay data in December, 2002. At a meeting between DoD and FDA on December 18, 2002, FDA noted that this product is on "voluntary clinical hold." FDA stated the potency data show the product is unusable, and reminded the DoD that the protocol remains on voluntary clinical hold, absent additional supporting data. We must find a means to provide a limited amount of BT to special units. We are reviewing any other potentially feasible options to address the threat of botulinum toxin. We ask that you continue your stated commitment to work with us to find a resolution to this critically important issue.

c. Anthrax vaccine and Cidofovir: Both products are currently licensed for other indications; however, DoD will be using them under IND for unapproved indications (postexposure prophylaxis of anthrax, and smallpox infection, respectively). We requested a simplified process for re-labeling of the vials in which we would overlabel the vials with an "IND use only" sticker or a waiver of this requirement. Your reply suggests that we consider submitting a waiver request, with appropriate justification. We agree. We will make such a submission for both of these INDs.

I have asked Colonel Terry Rauch of my office to act as the responsible official to accept your offer of assistance in coordinating DoD-FDA interactions. Colonel Rauch can be reached at (b)(6) @ha.osd.mil. Thank you for your efforts to effect rapid resolution of these matters.

Sincerely,

William Winkenwerder Jr., MD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

December 13, 2002

William Wmkenwerder, Jr, M D.
Assistant Secretary of Defense, Health Affairs
Washington, D C 20301-1200

Dear Dr Wmkenwerder

Thank you for your November 20 letter concermng use of products under IND for prophylaxis or treatment m the military setting and for your kind words on FDA's efforts since September 11, 2001. I agree that it is valuable for both our agencies to put DoD priorities in writing I will address each of your issues m order as presented in your letter

(a) Pyridostigmine bromide FDA continues to have concerns about DoD's proposed method of informed consent for the pyridostigmine bromide trial FDA and HI-IS legal counsel remain committed to workmg with DoD's counsel to fashion a legally supportable solution in a timely manner

(b) Pentavalent botulinum toxoid (PBT) vaccme FDA is m receipt of the October 22, 2002, submission by DoD to IND 3723, containing lot release information for PBT vaccine lots PBT 003 and PBT 004 This information was submitted pursuant to FDA's Center for Biologics Evaluation and Research (CBER) request in telephone conversations with DoD representatives on February 14, 2002, and October 10, 2002

For PBT lot 003, summary potency data for serotypes A, C, and E were reported as inconclusive, while the results for serotypes B and D were found to be below specifications. Serotypes D and E failed the resistance to challenge test For PBT lot 004, summary potency data for serotypes A, B, C, and E were reported as mconclustve, while the results for serotype D were reported to be below specifications In the resistance to challenge assay, serotypes B, D, and E were reported to be below specifications

Further, mtenm clinical immunogenicity data submitted to IND 3723 on April 16, 2001, have raised concerns about the ability of PBT lots 003 and 004 to induce a persistent antibody response m subjects immunized with this product

F'DA is concerned that military personnel may no longer be adequately protected from *C botulinum* toxins through administration of PBT because of rapidly decreasing clinical antibody titers and potency data that are either below specifications or have inconclusive results for all 5 serotypes In order to fully assess whether immunization with current lots of PBT may offer protective benefit under a military contmgency, we have requested

from DoD representatives the details of the potency assay data, including assay procedures and investigation reports, and the clinical immunogenicity data derived from the use of these lots Once CBER has the opportunity to review these data, this should allow an assessment of whether it is acceptable to relabel the remaining vials of PBT vaccine and/or to change the consent form to reflect a trivalent vaccine We are committed to working with you to make this important assessment

(c) Anthrax vaccine and Cidofovir Investigational products should be labeled as described in 21 CFR 312 6 Alternatively, a sponsor may request that FDA waive applicable requirements set forth in the IND regulations, including labeling for an investigational new drug (21 CFR 3 12 10) A waiver request must contain certain information described in 21 CFR 312 10 Please note that if FDA were to grant such a waver with respect to the labeling of a product to be used for investigational purposes but that remains labeled for its licensed use, FDA would be prepared, in this particular instance, to exercise its discretion and not object to the product's shipment for investigational use The Agency would be prepared to do so if DoD provides adequate information to end-users and to subjects concerning the investigational status and use of the product in question In addition, an adequate procedure for recording the disposition of the product would need to be in place, in accordance with 21 CFR 3 12 62(a)

FDA can work with, and provide guidance to, DoD on this matter Please also note that if DoD does "over-label" either anthrax vaccine or cidofovir for investigational use, DoD may not be able to change the labeling back to that representing either product's approved use unless FDA approves a supplement for additional relabeling

Lastly, I would mention that FDA's Office of Counterterrorism (OCT) in the Office of the Commissioner, specifically Dr (b)(6) email (b)(6) @oc fda gov), can serve as an FDA point of contact for your office and help coordinate FDA actions on DoD inquiries Colonel Rauch should feel free to contact her at any time (b)(6) also has a DoD liaison officer, (b)(6) (b)(6) Ph D , currently detailed to OCT. who can assist in these DoD priority issues Matters relating to specific product applications, such as INDs/IDEs, NDAs, or BLAs, should be discussed with the appropriate FDA Center

We look forward to working with you and your staff to resolve these issues and maximize health protection for our military forces

Sincerely,

Mark B McClellan, M D , Ph D
Commissioner of Food and Drugs

FORCE HEALTH PROTECTION & READINESS
DEPLOYMENT HEALTH SUPPORT DIRECTORATE

CMAT #: 3013-03
PCDOCS#: 44537
Date: 1-13-03

Action Tasking // Internal Routing Sheet

		Action	Info	Comments
	ASD (HA)/Special Assistant			
	Director FHP/R & DHSD (DIR)			
	FHP/R ACTION OFFICE [redacted] (Lead)	X		
	(Assist)			
	Deputy Director DHS (DEP)			
	DHS ACTION OFFICE _____ (Lead)			
	_____ (Assist)			
	DHS Operations SupportOffice (OSO)			
	DHS Editorial Review (ER)			
	☐ COMEBACK COPY TO _____ DHS AMB ☐ GET CMAT # WHEN SIGNED ☐ CHRON ALE			

SUSPENSE: 1-16-03

Prepare reply for signature of:
☐ Director
☐ _____

Hot

Comments:

Products Under IND for Prophylaxis or Treatment - SEE ASD (HA) note

☐ Congress	☐ Oversight	☐ FOIA	☐ OSD	☐ WBM	☐ VSO/MSO	☐ Outgoing
☒ Ltr to ASD HA	☐ IR	☐ E-Mail	☐ OGA	☐ Other	☐ PCDOCS	☐ Veteran

KEYWORDS: TNA

Monday, January 13, 2003 12:36 PM Profile CMAT Control # 2003013-0000012

HA/TMA Document Profile

44537

Subject: Products Under IND for Prophylaxis or Treatment

Author: (b)(6) M.D., Ph.D.

Congressional Name:

Date of Document: 12/13/2002

Input By: (b)(6)

OSD #:

Profiler's Directorate: Admin, HA

PR #:

Response Signed By:

Organization: Department of Health and Human

Dt Response Signed:

Department:

Doc Type: LETTER

Assigned To: DHS

Application: DOCSIMAGE

Prepared For: ASD

Previous Documents:

Suspense Date: 1/16/2003

Related Documents:

Coord Office(s):

Notes: SHORT SUSPENSE. REMARKS ~~FROM DR. WINKENWERDER~~ ATTACHED.

Beneficiary Info

Beneficiary Name:

Address 1:

Apartment #

Phone #

Email Address:

city:

State: Zip:

History

Created: 1/7/2003 HA PCDOCS Adr

Edited: 1/7/2003 HA PCDOCS Adr

Status: Available

Retention Schedule

Type: Archive

Retention Days: 365

☐ From External Source?

Access Control

☒ Secure Document

☐ Enable Content Searching

44537

To: Ms. Embrey's office 6 Jan 03

For evaluation and action, based upon response of FDA. I would like our action plan, based on this letter, within 8 business days.

B. el

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 203014200

HEALTH AFFAIRS

NOV 20 2002

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Mark
Dear Dr. McClellan:

This is a follow-up to our phone conversation on November 18.2002, regarding the use of investigational new drugs (IND) for prophylaxis or treatment to maximize military force health protection capabilities as the war on terrorism and potential new contingencies progress.

First, let me thank you and the staff of the Food and Drug Administration (FDA) far the efforts since September 11.2001, to approve drugs and vaccines needed for treatment or prophylaxis of biotarorism threats. FDA's approval of BioPort's Biologics Licerise Application Supplement has been instrumental in assuring the provision of vaccine necessary for the protection of our forces against tbis threat. Moreover, the licensing of the vaccinia vaccine (Dryvax) was of immense importance to DoD, as was the approval of doxycyclii and penicillin for post exposure treatment of inhalation anthrax. We have a strong relationship on which to build for the future.

DoD is eager to accelerate approval of several high priority new drug applications which could be required for use in a contingency. First among these is the approval of pyridostigmine bromide as a nerve agent pre-treatment against soman and tabun. Second is the approval of Anthrax Vaccine Absorbed (AVA) as a post-exposure treatment with antibiotics. These are our hi& priori@ concerns.

There are several unresolved issues that currently impact our ability to foimuiste deployment plans for the following IND medical products in priority order: Pyridostigmine Bromide; Botulinum Pentavalent Toxoid Vaccine; Anthrax vaccine for post-exposure treatment, and Cidofovir as a post exposure treatment for smallpox. Specifically:

a. rPyridostigmine bromide: A new protocol has been submitted to the FDA. Although it has not been placed on clinical hold, the FDA has expressed issues with the proposed method of informed consent. The informed consent issue is currently being discussed between DoD legal counsel and Health and Human Services legal counsel. This discussion hss been ongoing for the past month and must be resolved to finalize the plans for fielding the drug.

b. Botulinum pentavalent toxoid vaccine: Two of the five subtypes (D and E) have recently failed potency testing. The issue that requires your assistance is whether it will be necessary to relabel the remaining vials and change the informed consent form to reflect a trivalent vaccine.

c. Anthrax vaccine and Cidofovir: Both products are currently licensed, however, DoD will be using them under IND for unapproved indications (postexposure prophylaxis of Anthrax, and Smallpox infection, respectively). We request you consider a simplified process for re-labeling of the vials in which we would overlabel the vials with an "IND use only" sticker or a waiver of this requirement.

I wanted to document a clear understanding of the priorities of the Department in achieving results needed by our country in the months ahead. My office stands ready to convene an interagency meeting with appropriate representatives from the FDA to facilitate effective resolutions to these issues. My point of contact is Colonel Terry Rauch, who may be reached at [redacted] email: [redacted]@ha.osd.mil. I look forward to our work together. Thank you in advance for your willingness to see rapid resolution of these matters.

Sincerely,

Bill

William Winkenwerder, Jr.. MD

(b)(6) CON, OASD(HA)/TMA" (b)(6) @tma.osd.mil> on 11/20/2002 01:30:40 PM

To: (b)(6) @OSAGWI
cc: (b)(6) TMA" (b)(6)

Subject: IND Pkg

Hi Ed,
Just FYI. Dr. Winkenwerder signed the IND package today. I faxed to the FDA and mailed out the original as well. I am sending comeback copy to you through DND/Sky5. The signed document is scanned in PCDOCS at 43160. Have a great day!

(b)(6)
Document Management Division
Phone: (b)(6)
Fax:

SUBJECT: Investigational New Drugs for Force Health Protection

COORDINATIONS

USAMMDA	COL Jeffrey Gere	1/23/03 Recommends coord with DATSD(CBD)
DATSD(CBD)	LTC (b)(6)	Concur 1/23/03 with changes
DoD, OGC	Mr. (b)(6)	Concur 1/23/03
XO, DASD(FHP&R)	COL Rauch	_____
Bucket Supervisor	Col Cunningham	_____

[redacted] CIV, OASD/HA

From: (b)(6) Mr, DoD OGC
Sent: Friday, January 17, 2003 9:11 AM
To: (b)(6) CIV, OASD/HA
Subject: RE: DRAFT Memo to DATSD(CBD) re FDA ltr on INDs

O.K. with me. – (b)(6)

—Original Message—
From: (b)(6) CIV, OASD/HA
Sent: Thursday, January 16, 2003 2:45 PM
To: (b)(6)
Subject: DRAFT Memo to DATSD(CBD) re FDA ltr on INDs

Attached is my first draft of the requested memo to DR. Winegar concerning a tasking to work with FDA for BT IND approval and to provide a waiver for label for AVA Post Exposure and for label for Cidofovir. Sal

<< File: FDA Embrey to Winegar IND Jan 16 03.doc >>

(b)(6)
Program Director, Health Science Policy
Office of the Assistant Secretary of Defense
(Health Affairs) Force Health Protection & Readiness
Washington, DC 20301-1200
Phone: (b)(6)
FAX:

[redacted] CIV, OASD/HA

From: (b)(6) LTC, OSD-ATL
Sent: Thursday, January 23, 2003 12:16 PM
To: (b)(6)
cc:
Subject: RE: Interface with FDA for Use of Particular IND Products Draft Memo

(b)(6)

First off, neither of us attended the bot meeting yesterday, so I'm not sure whether this memo is OBE or not. Maybe COL [redacted] could clue us in. Having said that, the issues are still being worked irregardless of the memo.

Assuming the memo is still needed, here are some further comments:

Acronyms should be spelled out the first time used.

Dr. Winegar will task the PEO - but added that they need to collaborate with/work with MRMC to develop the BT data.

Dr. Winegar believes that MRMC should have the lead on the INDs, unless we come up with a compelling reason for someone else to have the lead.

In regards to reviewing the INDs – Dr. Winegar stated that it's MRMC for the IRB level, and then the Army SG for the HSRRB. Dr. Winegar's comments: adding these steps makes it clear that cooperation is needed and that it won't happen overnight!

(b)(6)

Lieutenant Colonel (b)(6)
phone: (b)(6)
e-mail:

-----Original Message-----
From: (b)(6)
Sent: Wednesday, January 22, 2003 5:52 PM
To: (b)(6)
Cc:
(b)(6)
Subject: RE: Interface with FDA for Use of Particular IND Products Draft Memo

LTC Borowski: Thanks for the returned on my call. Attached is a revised draft based on our conversation. Is this OK. Please review and comment. [redacted]

<< File: FDA Embrey to Winegar IND Jan 23 03.doc >>

-----Original Message-----
From: (b)(6) CIV, OASD/HA
Sent: Friday, January 17, 2003 5:23 PM
To: (b)(6)
Cc:
Subject: Interface with FDA for Use of Particular IND Products Draft Memo

Dr. Winegar: Attached is a draft memo to you from Ms. Embrey. Can you have your staff review and comment before it gets signed and sent. Thanks. VR (b)(6)

<< File: FDA Embrey to Winegar IND Jan 16 03.doc >>

(b)(6)
Program Director, Health Science Policy
Office of the Assistant Secretary of Defense
(Health Affairs) Force Health Protection & Readiness
Washington, DC 20301-1200
Phone: (b)(6)
FAX:

(b)(6) **CIV, OASD/HA**

From: (b)(6)
Sent: Friday, January 17, 2003 12:06 PM
To: (b)(6)
cc:
Subject: RE: DRAFT Memo to DATSD(CBD) re FDA ltr on INDs

Sal, I don't have anything specific re: the memo. I would suggest you coordinate with AJW prior to sending it. I suspect that she will turn to JPO/CBMS, and that their response will be that they do not have AVA or cidofovir in their developmental programs so therefore do not have any responsibility for them. They might be willing to help on the bot toxoid; I'm not a vaccinologist but I'm not sure what else can be done right now. The statement in the letter says "we must find a means to provide a limited amount of BT to special units". When we briefed AJW a few weeks ago, we told her that 1) bot toxoid is dead in the water and is not available for the current operation in SWA, and 2) that even if it were to be made available, it is already too late. The dosing regimen requires doses at 0, 2 and 12 weeks. It is generally recognized that antibody levels are not sufficient for protection until after the third dose. So even if we started tomorrow we could not have people fully immunized until mid April. I am not sure this fact is clear to Dr. Winkenwerder. Maybe you should make sure he understands that before he decides to fall on his sword over this. Jeff

-----Original Message-----
From: (b)(6) @ha.osd.mil]
Sent: Friday, January 17, 2003 11:29 AM
To: (b)(6)
Cc:
Subject: FW: DRAFT Memo to DATSD(CBD) re FDA ltr on INDs

Jeff: Attached is a draft memo to Dr. AJW. Re INDs. Can you review and comment? I can't get these to COL Davies -- the system keeps rejecting his address. Can you forward for his comment/concurrence? Thanks. Sal Cirone

-----Original Message-----
From: (b)(6)
Sent: Thursday, January 16, 2003 2:45 PM
To: (b)(6)
Subject: DRAFT Memo to DATSD(CBD) re FDA ltr on INDs

Attached is my first draft of the requested memo to DR. Winegar concerning a tasking to work with FDA for BT IND approval and to provide a waiver for label for AVA Post Exposure and for label for Cidofovir. Sal

<<FDA Embrey to Winegar IND Jan 16 03.doc>>

(b)(6)
Program Director, Health Science Policy
Office of the Assistant Secretary of Defense
(Health Affairs) Force Health Protection & Readiness
Washington, DC 20301-1200
Phone: (b)(6)
FAX:

#20030313-0000012

(b)(6) **CIV, OASD/HA**

From: (b)(6) @DET.AMEDD.ARMY.MIL]
Sent: Thursday, January 16, 2003 2:50 PM
To: (b)(6)
Cc:
Subject: RE: FDA ltr re-write

my suggestion is red = add "informed consent" to page 1, para 4, sentence 2.
Accepted! CHANGE MADE 01/16/03

-----Original Message-----
From: (b)(6)
Sent: Thursday, January 16, 2003 1:41 PM
To: (b)(6)
Cc: (b)(6)
Subject: FW: FDA ltr re-write

COL Gere and COL Davies: Attached below is a draft memo from Dr. Winkenwerder to the Commissioner of the FDA. COL Gere, LTC Brosch and Dr. Pace helped in the initial draft --- however -- there have been changes made by my supervisors. This draft letter makes COL Rauch the POC vice MG Martinez-Lopez because the front office wanted to keep the POC within HA. It also changes the Bot Tox paragraph because the front office wants to pursue a path or plan to get some type of BT approval for a limited number of Servicemembers, similar to giving it to lab workers who might be in need of protection. It is my understanding that HA received a brief on this last week and COL Burnette indicated that there were other possibilities -- although not very optimistic -- with lots 5&6 . In that regard I have been asked to draft a memo to the DATSD(CBD) to request that she task the appropriate organizations to work to FDA to find a solution to this issue. Also the paragraph on the AVA Post Exposure IND and the Cidofovir IND has been changed to reflect the FDA suggestion for a waiver. The memo to the DATSD(CBD) will also request that she task the appropriate organization to prepare and submit the IND waivers to FDA. Finally I have been asked to draft a memo to OTSG Army to develop a plan for Rx only since the PB may be licensed and require prescription use only.

I would like your concurrence on the letter below to the FDA. My suspense is today.

-----Original Message-----
From:
Sent: Thursday, January 16, 2003 1:07 PM
To: (b)(6)
Cc:
Subject: FW: FDA ltr re-write

This is the copy which I will make final. I changed the last paragraph to appoint you as POC as Dr. Winkenwerder asked for the first letter. I will draft a memo from Ms Embrey to Dr. Winegar to ask her to task MRMC to work with the FDA on both the Bot Tox and the waivers. I will draft a memo from Ms. Embrey to OTSG Army to quickly develop a plan for RX only use of Nerve Agent Pretreatments and Antidotes. Sal

<<FDA Winkenwerder IND Jan 16 03.doc>>

-----Original Message-----
From: [redacted]
Sent: Thursday, January 16, 2003 10:27 AM
To: (b)(6)
Cc:
Subject: FDA ltr re-write

Terry: Attached is a re-write with Mr. Casciotti's changes. I have added a few sentences to the BT paragraph to include Ms. Embrey's concern. Can both of you review what I have and comment? When I get something close to final, I would like to send it back to MRMC for their information. I'll also include COL Neal Burnette since he is the one who will have to work with USAMRMC on the lots five and six to see what we can do. Sal

<< File: FDA Winkenwerder IND Jan 16 03.doc >>

[redacted]
Program Director, Health Science Policy
Office of the Assistant Secretary of Defense
(Health Affairs) Force Health Protection & Readiness
Washington, DC 20301-1200
Phone: (b)(6)
FAX:

CMAT Control #
2003014-0000002

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

(4)

HEALTH AFFAIRS

ACTION MEMO

January 9, 2003 2:00 PM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Designation of Protocols as "Contingency Investigational New Drug (IND) Protocols for Force Health Protection"

- Attached at TAB A is a draft policy memorandum that designates six Investigational New Drug (IND) protocols as "Contingency IND Protocols for Force Health Protection."
- With the designation of "Contingency IND Protocol for Force Health Protection," the protocols listed in this memorandum will be subject to DoD Directive 6200.2 (Use of INDs for Force Health Protection), which requires approval by the Army Surgeon General's Institutional Review Board (IRB).
- For coherence, consistency, and efficient implementation, the Army's IRB, known as the Human Subjects Research Review Board (HSRRB), is designated in DoD 6200.2 as the centrally approving IRB that will be the approving authority for all of the Services Contingency IND Protocols.
- Local Army, Navy, Air Force and Marine Clinical Investigation Program (CIP) IRBs may individually review the Contingency IND Protocols for Force Health Protection, but will not be able to modify them.

RECOMMENDATION: ASD(HA) sign memo at TAB A.

COORDINATION: TAB B

ATTACHMENTS:
As stated

Prepared by: CDR [redacted] DHSD/ODASD(FHP&R), [redacted]
PCDOCS#

#2003014-000002

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

FEB 3 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT: Designation of Protocols as "Contingency Investigational New Drug Protocols for Force Health Protection"

The increasing threat of the use of weapons of mass destruction necessitates the implementation of investigational new drug (IND) protocols for force health protection. DoD Directive (DoDD) 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000, establishes policy and assigns responsibility for use of INDs for force health protection in the Department of Defense.

This policy memorandum officially designates the following U.S. Army Surgeon General IND protocols as "Contingency IND Protocols for Force Health Protection" and thus subject to the provisions of DoDD 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000.

a. "Contingency Protocol for the Administration of Vaccinia Immune Globulin – IM (Human) to Subjects who Experience Complications Resulting from Vaccination with Vaccinia Virus," IND 8429, version 13, dated August 2, 2002.

b. "Department of Defense Contingency Protocol for Emergency Use of Cidofovir (VISTIDE) as a Treatment for Smallpox," IND 65480, dated July 5, 2002.

c. "Department of Defense Protocol for the Use of Cidofovir (VISTIDE) as a Treatment for Adverse Reactions Associated with Vaccinia Virus Vaccination," IND (pending submission to FDA).

d. "Contingency Protocol for Vaccination with Pentavalent Botulinum Toxoid to Protect Against Botulinum Toxin Toxicity," IND 3723, version 6.1, dated June 10, 2002.

e. "Emergency Use Protocol for Botulinum Antitoxins," IND 10621, version 19, dated August 6, 2002.

f. "Contingency Protocol for Anthrax Vaccination to Protect Against *Bacillus anthracis* Spores," IND 10081, version 9, dated July 8, 2002 (to include Appendix K, Pediatric Addendum).

The Secretary of the Army, as Executive Agent, develops Contingency IND protocols for force health protection. These protocols are subject to approval by the Army Surgeon General's

Institutional Review Board (IRB) known as the Human Subjects Research Review Board (HSRRB). DoDD 6200.2 section 4.5 states, "The Army Human Subjects Research Review Board (HSRRB), under the Surgeon General of the Army, is designated as the IRB responsible for purposes of IRB activities under this Directive."

It is vitally important that we have coherence and consistency in the implementation of IND protocols; therefore, the Army Surgeon General's HSRRB will be the only IRB of record for these protocols. Local Army, Navy, Air Force and Marine Clinical Investigation Program (CIP) IRBs may individually review the Contingency IND Protocols for force health protection, but may not modify them. Every effort will be made to keep regional CIP IRBs fully informed of the status of these protocols (for information only).

Request you immediately implement the provisions of DoDD 6200.2 with regard to the above-listed Contingency IND Protocols for force health protection. My POC for this action is (b)(6) Program Director for Health Science Policy. He can be contacted at (b)(6) or at (b)(6)

William Winkenwerder, Jr., MD

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Commander, USAMRMC

(b)(6)
01/09/2003 12:22 PM

To: (b)(6)
cc:

Subject: Re: FW: Revised letter for Ms Embrey

[redacted]
See attached.
Thanks

(b)(6)

Contingency IND Protocols Dr WW Ja

(b)(6)

[redacted]
01/09/2003 07:49 AM

To: (b)(6)
cc:

Subject: FW: Revised letter for Ms Embrey
Document is set for Permanent Archival

(b)(6)

See note below - if you can this together and get me the draft this Morning would be appreciated.

Forwarded by (b)(6) on 01/09/2003 07:53 AM

(b)(6) on 01/09/2003 07:43:04 AM

To: (b)(6)

cc:

Subject: FW: Revised letter for Ms Embrey

Mark/Ed: With Sal's absence, can we please have Gene pull this together. It should be revised to be a memo from ASD(HA) to the Service M&RAs and cc SGs.

Thanks

(b)(6)

-----Original Message-----
From: (b)(6)
Sent: Monday, December 30, 20024:29 PM
To: (b)(6)
Cc:
(b)(6)

Subject: RE: Revised letter for Ms Embrey
Importance: High

Last revision as we triple verify the latest versions at the FDA - Use the 5th revision<<5Revised DRAFTMEMO for Ms Embrey -Force Health Protection INDs1.doc>>

-----Original Message-----
From: (b)(6) LTC USAMRMC
Sent: Monday, December 30, 2002 3:10 PM
To: (b)(6)
Cc:
(b)(6)

Subject: RE: Revised letter for Ms Embrey
Importance: High

Please discard version 3 of the letter and substitute version 4 with the correct Anthrax citation.
<< File: 4Revised DRAFTMEMO for Ms Embrey -Force Health Protection INDs1.doc >>

-----Original Message-----
From: (b)(6)
Sent: Monday, December 30, 2002 2:40 PM
To: (b)(6)
Cc:
(b)(6)

Subject: Revised letter for Ms Embrey
Importance: High

COL (b)(6)

Dr. (b)(6) informed me of the changes needed in the INDmemo from Ms Embrey to the Surgeons General. Attached is the revised letter with the information requested. Please let me know if you need any additional infomation. << File: 3Revised DRAFTMEMO for Ms Embrey -Force Health Protection INDs1.doc >>

LTC(P) (b)(6)
Deputy, Regulatory Compliance and Quality

US Army Medical Research and Materiel Command
504 Scott St.
Fort Detrick, Maryland, 21702
(b)(6)
email: (b)(6)

- 5Revised DRAFTMEMO for Ms Embrey -Force Health Protection INDs1.doc

(b)(6)
Chief, Action Management Branch
Deployment Health Support Directorate
(b)(6)

(b)(6)
Anthrax Program Liaison Officer for ASD (Health Affairs) and Deputy Program Director, Population Health,
Deployment Health Support Directorate
(b)(6)

SUBJECT: Designation of Protocols as "Contingency Investigational New Drug (IND) Protocols for Force Health Protection"

COORDINATIONS

USAMRMC	LTC (P[redacted]	Concur 01/09/03
Deputy Director, DHSD	[redacted]	Concur 01/09/03
CoS (HA)		_____
PDASD (HA)		_____

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:

MCMR-ZA

23 December 2002

MEMORANDUM THRU LTG [redacted] The Surgeon General, U.S. Army, 5109 Leesburg Pike, Falls Church, Virginia 22041-3258

FOR Ms. Ellen P. Embrey, Deputy Assistant Secretary Health Affairs (Force Health Protection and Readiness), Five Skyline Place, 5111 Leesburg Pike, Falls Church, Virginia 22041

SUBJECT: Request for ASD (HA) Designation of Protocols as "Contingency Investigational New Drug (IND) Protocols for Force Health Protection"

1. Request that ASD (HA) officially designate the following U.S. Army Surgeon General IND protocols as "Contingency IND Protocols for Force Health Protection" subject to the provisions of DODD 6200.2, Use of Investigational New Drugs for Force Health Protection, 1 August 2000.

a. Contingency Protocol for Administration of Vaccinia Immune Globulin (VIG) (Human) to Subjects Who Experience Complications from Vaccination with Vaccinia Virus.

b. Department of Defense Contingency Protocol for Emergency Use of Cidofovir (VISTIDE) as a Treatment for Smallpox.

c. Department of Defense Contingency Protocol for Emergency Use of Cidofovir (VISTIDE) as a Treatment for Adverse Reactions Associated with Vaccinia Virus Vaccination.

d. Contingency Protocol for Vaccination with Pentavalent Botulinim Toxoid to Protect against Botulinum Toxin Toxicity.

e. Emergency Use Protocol for Botulinum Antitoxins.

2. Background: The increasing threat of the use of weapons of mass destruction has forced DoD to implement IND protocols for force health protection. DODD 6200.2, Use of Investigational New Drugs for Force Health Protection, 1 August 2000, establishes policy and assigns responsibility for use of INDs for force health protection in the Department of Defense. The Secretary of the Army, as Executive Agent, developed the treatment protocols that are subject to approval

by the Army Human Subjects Research Review Board (HSRRB). DODD 6200.2 section 4.5 states, "the Army Human Subjects Research Review Board (HSRRB), under the Surgeon General of the Army, is designated as the IRB responsible for purposes of IRB activities under this Directive."

3. Protocol coherence, consistency, and efficient implementation are essential and therefore it is unreasonable for local Army, Navy, Air Force and Marine Corps Medical Treatment Facility Clinical Investigation Programs (CIPs) Institution Review Boards (IRBs) to individually review, modify, and approve the IND protocols for force health protection. Therefore, the Army Surgeon General's HSRRB will be the only IRB of record for these protocols. However, every effort will be made to keep regional CIP IRBs fully informed of the status of these protocols (for information only).

4. Questions may be referred to LTC (b)(6) AN, Deputy, Regulatory Compliance and Quality. She can be contacted at (b)(6) or (b)(6) or at (b)(6)

LESTER MARTINEZ-LOPEZ
Major General, MC
Commanding

3014-002

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

January 9, 2003 2:00 PM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD (Force Health Protection and Readiness) Ok under

SUBJECT: Designation of Protocols as "Contingency Investigational New Drug (IND) Protocols for Force Health Protection"

- Attached at TAB A is a draft policy memorandum that designates six Investigational New Drug (IND) protocols as "Contingency IND Protocols for Force Health Protection."
- With the designation of "Contingency IND Protocol for Force Health Protection," the protocols listed in this memorandum will be subject to DoD Directive 6200.2 (Use of INDs for Force Health Protection), which requires approval by the Army Surgeon General's Institutional Review Board (IRB).
- For coherence, consistency, and efficient implementation, the Army's IRB, known as the Human Subjects Research Review Board (HSRRB), is designated in DoD 6200.2 (TAB B) as the centrally approving IRB that will be the approving authority for all of the Services Contingency IND Protocols.
- Local Army, Navy, Air Force and Marine Clinical Investigation Program (CIP) IRBs may individually review the Contingency IND Protocols for Force Health Protection, but will not be able to modify them.

RECOMMENDATION: That the ASD (HA) sign memo at TAB A.

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR [redacted] DHSD, [redacted] PCDOCS# 44755, 44756

[redacted]

(b)(6)

[redacted]

SUBJECT: Designation of Protocols as "Contingency Investigational New Drug (IND) Protocols for Force Health Protection"

COORDINATIONS

USAMRMC	LTC (P) (b)(6)	Concur 01/09/03
Deputy Director, DHSD	Dr. (b)(6)	Concur 01/09/03
CoS (HA)	Ms	_____
PDASD (HA)	Mr	_____
OGC	(b)(6)	_____

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

TRICARE
TRICARE Management Activity

ACTION OFFICE NHS DATE 3-5-03 PCDOCS # 45444
44755 & 44756

The attached correspondence is returned for the following reason(s):

- ☑ **Distribution**
- ☐ **Coordination**
- ☐ **Revision**
- ☐ **Correct Signature Block**
- ☐ **Correct Envelope Size**
- ☐ **Correct Letterhead**
- ☐ **Provide Original/Supporting Documents**
- ☐ **Provide SD 391**
- ☑ **Retain for your Files**

(b)(6)

Make distribution tomorrow - give copy to Sol and chron file.

(b)(6)

Additional Comments:

Signed Response Scanned into PCDocs # 45444

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

	Sign	Coord		Sign	Coord
1/21/03 ASD, HA BW	✓		____ Dir, TMA		
____ PDASD, HA					
____ DASD, C&PP			____ CMO		
____ DASD, FHP&R			____ Dir, DHS		
____ DASD, HB&FP			____ CFO		
____ DASD, HPA			____ COO		
			____ Dir, Regional Operations/PEO		
____ CIO, MHS			____ Dir, IMT&R		
gc OGC, DoD TAB C		✓	____ OGC, TMA		
____ LA					
____ CoS, HA		✓	____ Dir, A&M		
____ Military Assistant			____ CoS, TMA		
____ Dir, PI, HA			____ Dir, PI, TMA		
____ Dir, P&S			____ Dir, Admin		
____ Other (Specify)			____ Other (Specify)		

DMD (SKY) ~~[illegible]~~ Date: 1/21 DMD (PNT) A Date: 1/21/03

Date Received: 1/21/03 **Suspense Date:** N/A

Subject: Designation of Protocols as "Contingency Investigational New Drug (IND) Protocols for Force Health Protection

PCDOCS #: 44755/756, 45444 **OSD/P&R #:** N/A

AO: (b)(6) **Office:** DHS **Phone #:** (b)(6)

NOTES:

Please call Anita or Greg
for pick up.
(703) 697-8979

CMAT Control #
2003022-0000033

6

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

JAN - 8 2003

HEALTH AFFAIRS

MEMORANDUM FOR EXECUTIVE SECRETARY, ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Collaboration with Advisory Committee on Immunization Practices to Evaluate Smallpox Vaccination Program

On December 5, 2002, as detailed in the attached document, Dr. Winkenwerder asked the Armed Forces Epidemiological Board (AFEB) to establish an independent workgroup of its members to evaluate the DoD Smallpox Vaccination Program (SVP) and provide to him, through the full board, a periodic program implementation evaluation. This evaluation should include a review of the clinical experience of smallpox vaccine recipients and evaluation of the data collection methods and analysis, both in the short and long-term. Dr. Winkenwerder expects the AFEB workgroup to work collaboratively with a similar workgroup of the CDC's Advisory Committee on Immunization Practices (ACIP), in evaluating safety surveillance aspects of smallpox vaccination, both for the DoD SVP and for smallpox vaccinations given in the civilian sector. This DoD effort is separate from the civilian smallpox vaccine program review being performed by the Institute of Medicine.

This AFEB-ACIP joint workgroup would be expected to meet at least monthly by teleconference and formally on a quarterly basis. More frequent meetings may be necessary as determined by the needs of the DoD, CDC and the workgroup. Funding for the AFEB workgroup travel and other expenses associated with this tasking will be provided to the AFEB Executive Secretariat at a later date. The Military Vaccine Agency will provide program status updates to the workgroup. The Vaccine Health Care Center Network will report on clinical investigations of adverse events. The Army Medical Surveillance Activity (AMSA) will report on ongoing surveillance and analysis of ambulatory and inpatient experiences among smallpox vaccine recipients. The Medical Materiel and Research Command will provide information on any use of vaccinia immune globulin or cidofovir under their investigational new drug protocols.

My point of contact is LtCol Roger Gibson, Program Director for Military Public Health, who may be reached at 703-681-1703 x5211 or email roger.gibson@ha.osd.mil.

David N. Tornberg, MD, MPH
Deputy Assistant Secretary of Defense
Clinical and Program Policy

Attachment:
As stated

cc:
DASD, FHP&R
Army Surgeon General
USA AMSA
Vaccine Health Care Center
USA MRMC

7. Direct the development of protocols to investigate the rate of smallpox vaccine-related chronic and subjective outcomes. This recommendation requires a long-term commitment but does not require immediate implementation. Conceptually, military Service members enrolled in the Millennium Cohort Study could form the cohort for this type of investigation.

   Recommended OPR: Deployment Health Research Center in collaboration with Uniformed Services University of the Health Sciences
   Requirement: Research on smallpox vaccine-related chronic and subjective outcomes
   Cost and/or recommended funding source: Estimated cost: $3M. Funding could be obtained through the Congressionally-directed Medical Research Program budget as a carve out

   ASD (HA): APPROVE____ DISAPPROVE____ WILL REVIEW LATER ✓

8. Direct the development of protocols to investigate adverse birth outcomes among live infants born to women who inadvertently received smallpox vaccine while pregnant.

   Recommended OPR: Deployment Health Research Center (currently investigating anthrax vaccine adverse related events)
   Requirement: Retrospective birth outcomes research
   Cost and/or recommended funding source: Estimated cost: $500K. Funding could be obtained through the Congressionally-directed Medical Research Program budget as a carve out

   ASD (HA): APPROVE ✓ **DISAPPROVE____**

9. Consider collaboration with Centers for Disease Control and Prevention (CDC) in the establishment of prospective registry for women who are found to have been pregnant at the time of smallpox vaccine administration. Such a registry will allow for prospective tracking of reproductive outcomes.

   Recommended OPR: Naval Health Research Center/Deployment Health Research Center
   Requirement: Prospective birth outcomes research
   Cost and/or recommended funding source: CDC

   ASD (HA): APPROVE ✓ **DISAPPROVE____**

10. Establish an independent external review board to evaluate the smallpox vaccination program, such as through collaboration between working groups of the Advisory Committee on Immunization Practices and the Armed Forces Epidemiological Board (AFEB). The Board should report to the ASD (HA).

Recommended OPR: MILVAX/AFEB
Requirement: External review board
Cost and/or recommended funding source: Undetermined-dependent of how the board is established

ASD (HA): APPROVE ✓ **DISAPPROVE**____

11. Based on data obtained through smallpox surveillance, establish a mechanism to facilitate and implement collaborative interagency research using state-of-the-art technologies and approaches. Examples of research opportunities include: genotyping analysis of families in which smallpox vaccine side effects are noted or perceived and the impact of concomitant administration of anthrax and smallpox vaccine.

Recommended OPR: VHC Network in collaboration with CDC
Requirement: Collaborative peer-reviewed research
Cost and/or recommended funding source: Dependent on protocol development and scope of specific research; multiple funding vehicles may be used

ASD (HA): APPROVE ✓ **DISAPPROVE**____

William Winkenwerder Jr.
5 December 2002

CMAT Control #
2003029-0000003

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

(7)

HEALTH AFFAIRS

ACTION MEMO

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Expanding Responsibility of the Anthrax Vaccine Immunization Program to Support the Milinary Biological Warfare Vaccine Program

REFERENCES: (a) Deputy Secretary of Defense Memorandum of June 282002, "Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)" (TAB B)

(b) Deputy Secretary of Defense Memorandum (S) of December 12, 2002, "(U) Stage 2 Smallpox Vaccination Implementation" (NOT ATTACHED - CLASSIFIED)

(c) DoD Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," November 26, 1993 (TAB B)

(d) DoD Directive 5100.88, "DoD Executive Agent," September 3, 2002 (TAB B)

- References (a) and (b) have continued the Secretary of the Army Executive Agency responsibilities for the Anthrax Vaccine Immunization Program (AVIP) and established similar responsibilities for the Smallpox Vaccination Program (SVP). Bioterrorism preparedness and readiness to address biological warfare threats of military significance make vaccine program management a top Force Health Protection priority.
- As the DoD Executive Agent for AVIP, the Army has demonstrated outstanding management, synchronization, and implementation of the anthrax and smallpox immunization programs. Therefore it's necessary to expand the AVIP Agency to support a Military Vaccine Agency (MILVAX), addressing all vaccine implementation requirements.
- Accordingly, I recommend that you request the Secretary of the Army, in accordance with references (a) through (d), to immediately transition the AVIP Agency to the Military Vaccine Agency, and include support for the Smallpox Vaccination Program.

RECOMMENDATION: That the ASD (HA) sign memo at TAB A.

COORDINATION: TAB C

ATTACHMENTS:
As stated

Prepared by: COL [redacted] FHP/R, (b)(6) [redacted] PCDOCS# 45275, 45273

TAB A

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-I 200

HEALTH AFFAIRS

MEMORANDUM FOR SECRETARY OF THE ARMY

SUBJECT: Expanding responsibility of the Anthrax Vaccine Immunization Program to Support the Military Biological Warfare Vaccine Program

REFERENCES: (a) Deputy Secretary of Defense Memorandum of June 28, 2002, "Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)"

(b) Deputy Secretary of Defense Memorandum (S) of December 12, 2002, "(U) Stage 2 Smallpox Vaccination Implementation"

(c) DoD Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," November 26, 1993

(d) DoD Directive 5100.88, "DoD Executive Agent," September 3, 2002

In references (a) and (b) the Deputy Secretary of Defense continued the Secretary of the Army Executive Agency responsibilities for the AVIP and established similar responsibilities for the Smallpox Vaccination Program (SVP). Bioterrorism preparedness and readiness to address naturally occurring diseases of military significance makes vaccine program management a top Force Health Protection priority. As the DoD Executive Agent for AVIP, the Army has demonstrated outstanding management, coordination, synchronization, and implementation of a joint Service-level immunization program.

Accordingly, I recommend that the Secretary of the Army, in accordance with references (a) through (c) begin immediately transitioning the AVIP Agency to undertake this larger role with support to the Smallpox Vaccination Program. Consistent with reference (d), I will recommend that the Deputy Secretary of Defense further expand the Executive Agency responsibili to include support for all Bioweapon vaccine program implementations through the Military Vaccine Agency.

William Winkenwerder Jr., MD

TAB B

Ref A

DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

JUN 28 202

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEF'ARTMENT OFDEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
DIRECTORS OF DEFENSE AGENCIES
COMMANDANT OFTHEUS COAST GUARD

SUBJECT: Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)

Food and Drug Administration (FDA) approval of the manufacturer's renovated facility restores the availability of anthrax vaccine. FDA has determined that the current anthrax vaccine is safe and effective in protecting against all forms of anthrax infection, a scientific conclusion recently supported by the Institute of Medicine.

Current intelligence assessments indicate that the anthrax threat to Department of Defense (DoD) forces is real. The Department's goal is to protect all forces against anthrax as a part of the Department's Force Health Protection program. Steps are being taken by the Department to ensure protection of U.S. service- and DoD personnel against the threat of anthrax and other potential bioweapon agents, including improved intelligence, detection, and surveillance capabilities, protective clothing and equipment, and new generation vaccines and other medical countermeasures.

At this time, the DoD will resume an Anthrax Vaccine Immunization Program (AW) consistent with FDA guidelines and the best practice of medicine, beginning with military personnel, and Emergency-Essential DoD civilians and contractors, at higher risk whose performance is essential for certain mission critical capabilities. Vaccination is mandatory for these personnel. except as provided under applicable medical and administrative exemption policies.

The scope of the AW shall encompass personnel assigned to or deployed for more than 15 days in higher threat areas whose performance is essential for certain mission critical capabilities. Near-term AVTP implementation may also include other personnel determined by the Assistant Secretary of Defense for Health Affairs, in consultation with the Chairman of the Joint Chiefs of Staff, to be at higher

U10535 /02

risk of exposure to anthrax as conditions change. Vaccinations shall begin, to the extent feasible, 45 days prior to deployment or arrival in higher threat areas.

For personnel who are covered under this new policy, who had previously begun the six shot series but had not completed it, resumption of their vaccination series will begin immediately. For personnel whose six sbot series was interrupted, but who are not covered under the new policy, completion of their vaccination series will be deferred until further notice; resumption will begin when feasible, subject to availability of vaccine. Personnel currently being immunized—designated special mission units, manufacturing and DoD research personnel, and Congressionally mandated anthrax vaccine researchers—will continue with their scheduled vaccinations and annual booster shots.

The Under Secretary of Defense for Personnel and Readiness shall issue policy guidance on the medical and administrative aspects of the AVIP. Effective program implementation continues to be the responsibility of the Secretary of the Amy as the Executive Agent for the AVIP and the designated senior military officers of the services*

Ref C

Department of Defense

DIRECTIVE

NUMBER 6205.3
November 26, 1993

ASD(NS&CP)

SUBJECT: DoD Immunization Program for Biological Warfare Defense

References: (a) Title 10, United States Code
(b) DoD Instruction 6205.2, "Immunization Requirements," October 9, 1986
(c) AR 40-562/NAVMEDCOMINST 6230.3/AFR 161-13/CG COMDTINST M6230.4D, "Immunizations and Chemoprophylaxis," November 7, 1988
(d) DoD Directive 5 136.1, "Assistant Secretary of Defense for Health Affairs," December 2, 1992
(e) through (g), see enclosure 1

1. PURPOSE

This Directive:

1.1. Establishes policy, assigns responsibilities, and prescribes procedures for members of the Department of Defense against validated biological warfare threats, and prioritization of research, development, testing, acquisition, and stockpiling of biological defense vaccines under reference (a).

1.2. Provides vaccination guidance that focuses exclusively on defense against biological warfare threats and complements immunization requirements for naturally occurring endemic disease threats outlined in references (b) and (c).

1.3. Addresses peacetime and contingency requirements for immunization against biological warfare threats against U.S. personnel.

1.4. Designates the Secretary of the Army as the "DoD Executive Agent" for the

DoD Immunization Program for Biological Warfare Defense.

1.5. Provides direction on levels of acquisition and stockpiling of biological defense vaccines and prioritizes research and development efforts in defending against current and emerging biological warfare threats.

2. APPLICABILITY AND SCOPE

This Directive applies to:

2.1. The Office of the Secretary of Defense, the Military Departments (including their National Guards), the Chairman of the Joint Chiefs of Staff, the Unified Commands, and the Defense Agencies (hereafter referred to collectively as "the DoD Components"). The term "Military Services," as used herein, refers to the Army, the Navy, the Air Force, and the Marine Corps.

2.2. Essential DoD civilian personnel, and personnel of other Federal Departments, when assigned as part of the U.S. Armed Forces.

3. DEFINITIONS

Terms used in this Directive are defined in enclosure 2.

4. POLICY

It is DoD policy that:

4.1. For immunization, the following personnel, subject to special exceptions approved by the Chairman of the Joint Chiefs of Staff, should be immunized against validated biological warfare threat agents, for which suitable vaccines are available, in sufficient time to develop immunity before deployment to high-threat areas:

4.1.1. Personnel assigned to high-threat areas.

4.1.2. Personnel predesignated for immediate contingency deployment (crisis response).

4.1.3. Personnel identified and scheduled for deployment on an imminent or ongoing contingency operation to a high-threat area.

4.2. For vaccine research, development, testing, evaluation, acquisition, and stockpiling, efforts for the improvement of existing vaccines and the development of new vaccines against all validated biological warfare threat agents shall be integrated and prioritized. The Department of Defense shall develop a capability to acquire and stockpile adequate quantities of vaccines to protect the programmed force against all validated biological warfare threats.

5. RESPONSIBILITIES

5.1. The Under Secretary of Defense for Acquisition and Technology shall ensure the coordination and integration of the **DoD** Immunization Program for Biological Warfare Defense with all acquisition-related elements of the **DoD** Biological Defense **Program.**

5.2. The Under Secretary of Defense for **Policy** shall review all facets of the **DoD** Immunization Program for Biological Warfare Defense to ensure that it is consistent with **DoD** policy and is adequately integrated into overall **DoD** biological defense policies.

5.3. The Assistant Secretary of Defense for Health Affairs shall:

5.3.1. Serve as the advisor to the Secretary of Defense as in **DoD** Directive 5 136.1 (reference (d)) on the **DoD** Immunization Program for Biological Warfare Defense.

5.3.2. In consultation with the **DoD** Executive Agent, the Secretaries of the Military Departments, and the Chair of the Armed Forces Epidemiological Board, identify vaccines available to protect against biological threat agents designated by the **Chairman** of the Joint Chiefs of Staff and recommend appropriate immunization protocols.

5.3.3. Issue instructions to the Military Departments and the other appropriate **DoD** Components on the immunization of **DoD** personnel, under the guidelines **of this** Directive, and monitor and **evaluate** the implementation of those instructions.

5.4. The Secretary of the Army, as the DoD Executive Agent for the Immunization **Program** for Biological Warfare Defense, shall:

5.4.1. Besides those responsibilities in the Deputy Secretary of Defense Memorandum and the Joint Service Agreement (references (e) and (f)), do the following to enhance the DoD Immunization Program for Biological Warfare Defense, and report ammally through the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to the Secretary of Defense the capability to carryout those policies:

5.4.1.1. Vaccine Research and Development

5.4.1.1.1. Priorities developed in coordination with the ASD(HA), the Chairman of the Joint Chiefs of Staff, and the Secretaries of the Military Departments shall include the development of vaccines against validated biological warfare threat agents for which none exist, improvement of vaccines that are unacceptable in the time they take to produce immunity or in the level of immunity they produce or are inadequate because of the number of doses required to achieve. immunity, assessment of the effectiveness of vaccines against biological warfare threat agents in their likely modes of use (e.g., aerosols), and development of multivalent vaccines that will produce protective immunity after a single vaccination. Vaccines must be either licensed by the Food and Drug Administration (FDA) or have been designated, under FDA requirements, "for use as investigational new drugs (INDs)," as in 21 CFR 50 (reference (g)).

5.4.1.2. Vaccine Acquistion and Stockpiling

5.4.1.2.1. Develop and maintain a DoD capability to acquire and stockpile adequate quantities of vaccines to protect the programmed force against all validated biological warfare threat agents for which suitable vaccines exist.

5.4.1.2.1. On an annual basis, provide information and recommendations, in coordination with the Secretaries of the Military Departments and the Chair of the Armed Forces Epidemiological Board, to the ASD(HA) on vaccines to acquire and appropriate immunization schedules that include reimmunization required to develop and maintain protective immunity. Those recommendations should include, but not be limited to the following:

5.4.1.2.1.1. All relevant data on the effectiveness of each vaccine against the corresponding biological warfare threat agent.

5.4.1.2.1.2. The expected type, frequency, and severity of vaccine-associated adverse reactions.

5.4.2. Serve as the focal point for the submission of information from the Services, as specified by subsection 5.5., below, and monitor the Services' implementation of the DoD Immunization Program for Biological Warfare Defense. Recommend appropriate changes and improvements to the *Secretary* of Defense through the ASD(HA), and the Secretaries of the Military Departments. Report to the Secretary of Defense annually on the Immunization Program for Biological Warfare Defense.

5.4.3. The Executive Agent Acquisition Executive (AE) shall plan, program, and budget for biological defense. The AE shall coordinate directly with the ASD(HA), the Under Secretary of Defense for Policy, the Under Secretary of Defense for Acquisition, the Secretaries of the Departments, and other offices as required to ensure program integration.

5.5. The Secretaries of the Military Departments shall:

5.5.1. Implement, monitor, evaluate, and document the DoD Immunization Program for Biological Warfare Defense in their Department and establish procedures for coordinating and reporting the following information to the Executive Agent:

5.5.1.1. The identification, reporting, and epidemiologic evaluation of vaccine-associated adverse reactions, in accordance with FDA requirements.

5.5.1.2. The collection and forwarding of data required by the Executive Agent needed to meet requirements of the FDA for products that are the INDs.

5.5.2. Transmit the instructions of the ASD(HA) about the immunization program for biological warfare defense to subordinate units.

5.5.3. Program and budget for the required vaccinations for members of their Department and provide the DoD Executive Agent with projected program requirements.

5.6. The Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified Commands; the Chiefs of the Military Services; and the Director, Defense Intelligence Agency (DIA), annually and as required, shall validate and prioritize the biological warfare threats to DoD personnel and forward that list to the DoD Executive Agent through the ASD(HA).

5.7. The Commanders of the Unified Commands, annually and as required, shall

provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theaters.

5.8. The Chair of the Armed Forces Epidemiological Board, in consultation with the DoD Executive Agent and the Secretaries of the Military Departments, annually and as required, shall identify to the ASD(HA) vaccines available to protect against validated biological warfare threat agents, and recommend appropriate immunization protocols.

6. PROCEDURES

The DoD Immunization Program for Biological Warfare Defense shall be conducted, as follows:

6.1. The Commanders of the Unified Commands, annually and as required, shall provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theater.

6.2. The Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified Commands; the Chiefs of the Military Services; and the Director, DIA, annually, shall validate and prioritize the biological warfare threats to DoD personnel and forward them to the DoD Executive Agent through the ASD(HA).

6.3. Within 30 days of receiving the validated and prioritized biological warfare threat list from the Chairman of the Joint Chiefs of Staff, the DoD Executive Agent shall, in consultation with the Secretaries of the Military Departments and the Chair of the Armed Forces Epidemiology Board, provide recommendations to the ASD(HA) on vaccines and immunization protocols necessary to enhance protection against validated biological warfare threat agents.

6.4. Within 30 days of receiving the coordinated recommendations of the DoD Executive Agent, the ASD(HA) shall direct the Secretaries of the Military Departments to begin immunization of the specified DoD personnel against specific biological warfare threat agents.

6.5. For biological threats for which the only available vaccine is an ND, it shall be administered under 21 CFR 50 and 312 (reference (g)) and the established ND protocol and/or other applicable legal procedures.

7. INFORMATION REQUIREMENTS

The annual reporting requirements in section 5., above, have been assigned Report Control Symbol DD-POL(A) 1921.

8. EFFECTIVE DATE AND IMPLEMENTATION

This Directive is effective immediately. The Secretaries of the Military Departments shall forward one copy of implementing documents to the Assistant Secretary of Defense for Health Affairs within 120 days.

William J. Perry
Deputy Secretary of Defense

Enclosures - 2
1. References
2. Definitions

El. ENCLOSURE 1

REFERENCES. continued

(e) Deputy Secretary of Defense Memorandum, "Biological Warfare Defense Program," August 26, 1991

(f) Joint Service Agreement, "Joint Service Coordination of Chemical Warfare and Chemical-Biological Defense Requirements, Research, Development, and Acquisition," July 5, 1984

(g) Title 21, Code of Federal Regulations, Parts 50, "Informed Consent of Human Subjects," and 3 12, "Investigational New Drug Application," current edition

E2. ENCLOSURE 2

DEFINITIONS

E2.1.1. Biological Warfare Agent. A microorganism or biological toxin intended to cause disease, injury, or death in humans.

E2.1.2. Biological Warfare Threat. A biological materiel planned to be deployed to produce casualties in humans.

E2.1.3. High-Threat Area. A geographic area in the proximity of a nation or nations considered to pose a potential biological threat to DoD personnel by the Chairman of the Joint Chiefs of Staff in consultation with the Commanders in Chief of the Unified Commands and the Director, DIA.

E2.1.4. Immunity. The capacity to resist the effects of exposure to a specific biological agent or toxin.

E2.1.5. Immunization. The process of rendering an individual immune. Immunization refers to "the administration of a vaccine to stimulate the immune system to produce an immune response (active immunization)." That process may require weeks to months and administration of multiple doses of vaccine.

E2.1.6. Programmed Force. The DoD active and Reserve force approved by the Secretary of Defense in the Future Years Defense Program.

E2.1.7. Vaccination. The administration of a vaccine to an individual for inducing immunity.

E2.1.8. Vaccine. A preparation that contains one or more components of a biological agent or toxin and induces an immune response against that agent when administered to an individual.

E2.1.9. Validated Biological Warfare Threat Agent. A biological warfare agent that is validated as a threat to DoD personnel by the Chairman of the Joint Chiefs of Staff, in consultation with the Commanders of the Unified and Specified Commands; the Chiefs of the Military Services; and the Director, DIA.

Ref D

Department of Defense

DIRECTIVE

NUMBER 5100.88

September 3, 2002

DA&M

SUBJECT: DoD Executive Agent

References: (a) Title 10, United States Code
(b) DoD Instruction 4000.19, "Interservice and Intragovernmental Support," August 9, 1995
(c) DoD 5025. 1-M, "DoD Directives System Procedures," current edition
(d) DoD Directive 5100.3, "Support of the Headquarters of Combatant and Subordinate Joint Commands," November 15, 1999
(e) through (g), see enclosure 1

1. PURPOSE

Pursuant to the authority of the Secretary of Defense under reference (a), this Directive:

1.1. Provides a DOD-wide definition of DoD Executive Agent.

1.2. Provides DoD approval authority for assigning DoD Executive Agent responsibilities, functions, and authorities within the Department of Defense.

1.3. Prescribes the policy for the management and control of DoD Executive Agent assignments and arrangements associated with such assignments within the Department of Defense.

1.4. Provides for the exchange of information between DoD Executive Agents and the DoD Components regarding resources and the quality of support throughout the full range of operations.

2. APPLICABILITY

This Directive applies to the Office of the Secretary of Defense; the Military Departments; the Chairman of the Joint Chiefs of Staff; the Combatant Commands; the Office of the Inspector General, Department of Defense; the Defense Agencies; the DoD Field Activities; and all other organizational entities within the Department of Defense (hereafter collectively referred to as "the DoD Components").

3. DEFINITIONS

As used in this Directive, the following terms have the meaning set forth below:

3.1. DoD Executive Agent. The Head of a DoD Component to whom the Secretary of Defense or the Deputy Secretary of Defense has assigned specific responsibilities, fimctions, and authorities to provide defined levels of support for operational missions, or administrative or other designated activities that involve two or more of the DoD Components. The nature and scope of the DoD Executive Agents responsibilities, fimctions, and authorities shall:

3.1.1. Be prescribed at the time of assignment.

3.1.2. Remain in effect until the Secretary of Defense or the Deputy Secretary of Defense revokes or supersedes them.

3.2. OSD Principal Staff Assistants. The Under Secretaries of Defense, the Director of Defense Research and Engineering, the Assistant Secretaries of Defense, the General Counsel of the Department of Defense, the Assistants to the Secretary and Deputy Secretary of Defense, and the OSD Directors or equivalents, who report directly to the Secretary of Defense or Deputy Secretary of Defense.

4. POLICY

It is DoD policy that:

4.1. The DoD Executive Agent designation shall be conferred when

4.1.1. No existing means to accomplish DoD objectives exists.

4.1.2. DoD resources need to be focused on a specific area or areas of responsibility in order to minimize duplication or redundancy, or

4.1.3. Such designation is required by law, Executive Order, or Government-wide regulation.

4.2. Only the Secretary of Defense or the Deputy Secretary of Defense may designate a DoD Executive Agent and assign associated responsibilities, functions, and authorities within the Department of Defense.

4.3. The Head of a DoD Component shall be designated as a DoD Executive Agent The DoD Executive Agent may delegate, to a subordinate designee within that official's Component, the authority to act on that official's behalf for any or all of those DoD Executive Agent responsibilities, functions, and authorities assigned by the Secretary of Defense or the Deputy Secretary of Defense. The DoD Executive Agent, or subordinate designee, may arrange for and execute inter-Service support agreements, in accordance with DoD Instruction 4000.19 (reference (b)), memoranda of understanding, and other necessary arrangements, as required, to fulfill assigned DoD Executive Agent responsibilities, functions, and authorities.

4.4. Within the scope of assigned responsibilities and functions, the DoD Executive Agent's authority takes precedence over the authority of other DoD Component officials performing related or collateral joint or multi-component support responsibilities and functions.

4.5. The DoD Executive Agent assignments and arrangements associated with such assignments shall be identified in a DoD issuance in accordance with reference (c). The issuance shall:

4.5.1. Cite the Secretary of Defense's or the Deputy Secretary of Defense's authority assigning DoD Executive Agency.

4.5.2. Identify the responsibilities, functions, relationships, and authorities of the DoD Executive Agent.

4.5.3. Identify funding and other resource arrangements for the DoD Executive Agent to carry out assigned responsibilities, functions, and authorities.

4.5.4. Specify other DoD Components, if any, that provide operational missions or administrative or other designated activities in support of the DoD Executive Agent.

4.6. The **DoD** Executive Agency arrangements shall be structured in a manner that permits the effective and efficient accomplishment of assigned responsibilities, functions, and authorities.

4.7. The **DoD** Executive Agent funding methods and resource requirements, including force structure to the extent permitted by law, shall be included as a part of the Planning, Programming, Budgeting and Execution process.

4.8. The performance of **DoD** Executive Agents shall be assessed periodically for continued need, currency, effectiveness, and efficiency in satisfying end user requirements.

4.9. There shall be **an** approved list of **DoD** Executive Agent designations.

4.10. Procedures governing the establishment, disestablishment, modification, and execution of **DoD** Executive Agent assignments and associated arrangements shall be established.

4.11. The funding and costs **in** support of each **DoD** Executive Agent assignment and associated arrangements shall be identified separately and shall be visible within the **DoD** budget.

5. RESPONSIBILITIES AND FUNCTIONS

5.1. The Director of Administration **and** Management, Office of the **Secretary** of Defense, shall:

5.1.1. Develop policy on **DoD** Executive Agent assignments and arrangements associated with such **assignments** for approval by the Secretary of Defense or the Deputy Secretary of Defense; oversee the implementation of the policy throughout the Department of Defense; and, issue guidelines, as appropriate, to define further the policies, responsibilities and functions, and authorities contained in this Directive.

5.1.2. Coordinate on all **DoD** issuances that assign or modify **DoD** Executive Agent designations.

5.1.3. Develop, maintain, monitor, revise, **and** make available to all the **DoD** Components, the list of **DoD** Executive **Agent designations** approved by the Secretary of Defense or the Deputy Secretary of Defense.

51.4. Issue **DoD** issuances implementing this Directive.

5.2. The DoD Executive Agents shall:

5.2.1. Execute **DoD** Executive Agent responsibilities, consistent with applicable law, **DoD** Directive 5 100.3 (reference (d)), **DoD** Directive 5 100.73 (reference (e)), and this Directive.

5.2.2. Ensure proper coordination with the **DoD** Components for the responsibilities and activities assigned to provide continuous, sustainable, **and** global support as required by end users. Ensure effective planning throughout operations by developing a coordinated process and support plans for transition from peacetime to wartime **and/or** contingency operations.

5.2.3. Identify requirements and resources, including force structure to the extent permitted by law, necessary to execute assigned responsibilities and functions. Submit these requirements to the cognizant Head of the **DoD** Component to be included in their respective budget **documenation.**

5.2.4. Monitor resources used in performing assigned responsibilities and functions.

5.2.5. Develop, maintain, and report results of performance of **DoD** Executive Agent responsibilities and functions, as may be required by law, Secretary of Defense decision, or other Congressional requirements.

5.2.6. Obtain reports and information, consistent with **DoD** Directive 8910.1 (reference **(f)),** as necessary, to carry out assigned **DoD** Executive Agent responsibilities, functions, and authorities.

5.2.7. Establish, maintain and preserve information as records, consistent with **DoD** Directive 5015.2 (reference (g)), that document the transaction of business and mission of the **DoD** Executive Agent.

5.2.8. Designate a focal point to coordinate matters regarding assigned**DoD** Executive Agent responsibilities, functions, and authorities.

5.3. The OSD **Principal** Staff Assistants shall:

5.3.1. Oversee the activities of **DoD** Executive Agents in their functional areas of responsibility.

5.3.2. Assess periodically, but not less than every three years, DoD Executive Agent assignments and arrangements associated with such assignments, under their cognizance for continued need, currency, and effectiveness and efficiency in satisfying end user requirements. Recommend establishment, continuation, modification, or cancellation of those DoD Executive Agent assignments and arrangements associated with such assignments, under their cognizance, as appropriate.

5.3.3. Designate a focal point to implement the guidance contained in this Directive and to coordinate matters regarding identification, control, and evaluation of the DoD Executive Agent assignments and arrangements associated with such assignments within their area of cognizance.

5.4. The Heads of the DoD Components, when receiving DoD Executive Agent support, shall:

5.4.1. Provide estimates of requirements and associated resources to the designated DoD Executive Agent on a timely basis.

5.4.2. Assess, as required, DoD Executive Agent support for effectiveness and efficiency in meeting requirements and make appropriate recommendations for improvement.

5.4.3. Designate a focal point to coordinate matters regarding the establishment of new, the identification of existing, and the control and evaluation of DoD Executive Agent support arrangements.

5.5. The Chairman of the Joint Chiefs of Staff shall:

5.5.1. Coordinate with the OSD Principal Staff Assistants and the Heads of the DoD Components to monitor DoD Executive Agent assignments and arrangements associated with such assignments for impact on the full range of operations.

5.5.2. Communicate, to the Combatant Commanders, DoD Executive Agent assignments and arrangements associated with such assignments in order to support and facilitate national military objectives throughout the full range of operations.

5.6. The Under Secretary of Defense (Comptroller) shall:

5.6.1. Ensure that the **DoD** Component budget submissions, including requirements supporting **DoD** Executive Agent assignments and arrangements associated with such assignments, are integrated into the **DoD** Planning, Programming, and Budgeting System.

5.6.2. Ensure that all **funds** and costs required to support **DoD** Executive Agent **assignments** and the arrangements associated with such assignments are displayed separately and justified in the **FYDP** and the budget exhibit submissions of de **Heads** of the **DoD** Components exercising **DoD** Executive Agent responsibilities and **functions.**

5.7. The General Counsel of the Department of Defense shall coordinate on all **DoD** issuances that assign or modify **DoD** Executive Agent designations, and provide legal counsel and advice, as appropriate, to implement this Directive.

6.. **EFFECTIVE DATE**

6.1. **This** Directive is effective immediately.

6.2. This Directive does not revise, modify, or rescind any **DoD** Executive Agent assignments and their implementing arrangements in existence as of the effective date of this Directive.

Paul Wolfowitz
Deputy Secretary of Defense

Enclosures - 1
El. References, continued

El. ENCLOSURE 1

REFERENCES, continued

(e) DoD Directive 5100.73, "Major Department of Defense Headquarters Activities," May 13, 1999
(f) DoD Directive 89 10.1, "Management and Control of Information Requirements," June 11, 1993
(g) DoD Directive 5015.2, "DoD Records Management Program," March 6, 2000

Tab C

SUBJECT: Expanding Responsibility of the Anthrax Vaccine Immunization Program to Support the Military Biological Warfare Vaccine Program

COORDINATIONS

MILVAX	COL (b)(6)	_____
DoD, OGC	Mr. (b)(6)	**Concur 1/17/03**
CoS (HA)	Ms.	_____
PDASD (HA)	Mr.	_____

[redacted]

Ed **Rushin**

[redacted]

01/17/2003 08:56 AM

To: (b)(6)
cc:

Subject: REQUEST FOR COORDINATION - Expanding Responsibility of the Anthrax Vaccine Immunization to Support the Military Biological Warfare Vaccine Program
Document is Permanently Archived

(b) / COL (b)(6)

Colonel (b) asked that you review the attached drafts for **ASD(HA)** and **USD(PR)** signature.

MILVAX USD PR Action Memo 1-15

MILVAX ASD HA Action Memo 1-15

(b)(6)
Chief, Action Management Branch
Deployment Health Support Directorate
(b)(6) Fax (b)(6)

[redacted]

01/21/2003 10:22 AM

To: (b)(6)
cc:

Subject: REQUEST FOR COORDINATION - Expanding Responsibility of the Anthrax Vaccine Immunization to Support the Military Biological Warfare Vaccine Program
Document is Permanently Archived

Colonel,

Have you had a chance to review both packages? (b)(6) recommaneded changes have been incorporated and are attached. MILVAX USD PR Action Memo 1-15

MILVAX ASD HA Action Memo 1-15

His changes were only to DSD package. At your convenience please.

---------- Forwarded by [redacted] on 01/21/2003 10:22 AM ----------

[redacted]

(b)(6)

01/17/2003 08:56 AM

To: [redacted]
cc:

Subject: REQUEST FOR COORDINATION - Expanding Responsibility of the Anthrax Vaccine Immunization to Support the Military Biological Warfare Vaccine Program
Document is Permanently Archived

(b)(6) COL (b)(6)

Colonel [redacted] asked that you review the attached drafts for ASD(HA) and USD(PR) signature.

MILVAX USD PR Action Memo 1-15 MILVAX ASD HA Action Memo I-15

(b)(6)
Chief, Action Management Branch
Deployment Health Support Directorate
[redacted] Fax: [redacted]

(b)(6)
Chief, Action Management Branch
Deployment Health Support Directorate
[redacted] Fax: [redacted]

CMAT Control #
2003034-0000013

8

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

January 31, 2002, 3:00 P.M.

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: DoD National Vaccine Healthcare Center (VHC) Network Advisory Board Charter

- TAB A is a request for coordination on the draft charter, DoD National Vaccine Healthcare Center Network Advisory Board (VHC NAB).
- Attached at TAB B is the proposed charter, which establishes the VHC network and the board membership. The board functions as a consultative panel of experts that convenes for the review of VHC NAB issues and makes recommendations to the Assistant Secretary of Defense for Health Affairs.
- The VHC network, along with the NAB, is a collaborative effort between the Department of Defense and the Centers for Disease Control and Prevention, to establish a system for monitoring vaccine adverse events occurring among members of the armed forces. See information paper attached at TAB B.
- Coordination of the draft charter by addressees is requested no later than March 7, 2003.

RECOMMENDATION: That ASD(HA) sign memo at TAB A.

COORDINATIONS: (TAB C)

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6)

2003034-0000013

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

January 31, 2002, 3:00 P.M.

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: DoD National Vaccine Healthcare Center (VHC) Network Advisory Board Charter

- TAB A is a request for coordination on the draft charter, DoD National Vaccine Healthcare Center Network Advisory Board (VHC NAB).

- Attached at TAB B is the proposed charter, which establishes the VHC network and the board membership. The board functions as a consultative panel of experts that convenes for the review of VHC NAB issues and makes recommendations to the Assistant Secretary of Defense for Health Affairs.

- The VHC network, along with the NAB, is a collaborative effort between the Department of Defense and the Centers for Disease Control and Prevention, to establish a system for monitoring vaccine adverse events occurring among members of the armed forces. See information paper attached at TAB B.

- Coordination of the draft charter by addressees is requested no later than March 7, 2003.

RECOMMENDATION: That ASD(HA) sign memo at TAB A.

COORDINATIONS: (TAB C)

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6) 45729

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
JOINT STAFF SURGEON
DIRECTOR, HEALTH AND SAFETY, US COAST GUARD
PRESIDENT, ARMED FORCES EPIDEMIOLOGY BOARD

SUBJECT: Draft charter for the DoD National Vaccine Healthcare Center Advisory Board

I request coordination no later than noon Friday, March 7, 2003, on the draft charter for the DoD National Vaccine Healthcare Center Network Advisory Board (VHC NAB), (Attachment #1).

This charter establishes the VHC NAB, which provides consultative expertise for the review of network mission specific issues and makes recommendations to the Assistant Secretary of Defense for Health Affairs.

I have enclosed an information paper on the DoD NationalVaccine Healthcare Center Network for your information, (Attachment #2).

If you have questions regarding this matter, please contact Commander (b)(6) (b)(6), e-mail: (b)(6) @deploymenthealth.osd.mil. Forward your coordination (TAB D) to (b)(6)

William Winkenwerder Jr., MD

Attachments:
As stated

CHARTER

DoD National Vaccine Healthcare Center Network Advisory Board

1. **PURPOSE:** The DoD Vaccine Healthcare Center Network Advisory Board (VHC NAB) provides consultative expertise for the review of network mission specific questions and makes recommendations to the Assistant Secretary of Defense for Health Affairs, ASD(HA). The ASD(HA) shall appoint a Director, DoD National Vaccine Healthcare Center Network to chair the NAB. The NAB provides periodic oversight recommendations regarding the VHC network program and proposes changes in the mission or functions of the network.

2. **BACKGROUND:** The VHC network is a collaborative effort between the Department of Defense and the Centers for Disease Control and Prevention that fulfills Section 751 of the National Defense Authorization Act of 2001. This Act instructs the Secretary of Defense to establish guidelines under which servicemembers "may obtain access to a Department of Defense Center of Excellence treatment facility for expedited treatment and follow up" [10USC 1110(2)(b)(3)] as part of establishing "a system for monitoring adverse events of members of the armed forces to the anthrax vaccine" [10USC 1110(2)(b)(1)]. The network will function as allergy-immunology Centers of Excellence and be accessible to DoD beneficiaries and providers either directly or on a referral basis. As the network matures, it will develop the structure and tools to support a vaccine safety assessment program from surveillance and enhanced vaccine adverse events reporting to case management of complex adverse events. Emphasis will be placed on standardization of clinical and educational programs that focus on healthcare provider and beneficiary understanding of immunizations and vaccine safety. Clinical research partnerships will be developed to validate clinical guidelines and support improvements in vaccine healthcare delivery. The first of 15 planned regional centers opened in Washington, DC, at Walter Reed Army Medical Center on September 6, 2001.

   Historically the DoD has depended on the Armed Forces Epidemiological Board (AFEB) for vaccine advice and guidance, just as the Department of Health and Human Services has depended on the Advisory Committee on Immunization Practices (ACIP). Representation on the NAB by members of both the AFEB and ACIP bring scientific credibility and institutional independence to the oversight and recommendations provided to the ASD(HA) and the Director, National Vaccine Healthcare Center Network.

3. **GOALS:** The VHC NAB goals include but are not limited to:

   - Providing review of programs, tools and research developed by the VHC network.
   - Providing guidance and recommendations on how to best optimize collaborative efforts between government and civilian agencies with the VHC network.
   - Assisting and directing the VHC network in providing its services to personnel in order to enhance vaccine use, primarily for the military in operational settings.
   - Consulting and reviewing clinical-management issues, protocols, and other vaccine-delivery issues for the VHC network.

4. **MEMBERSHIP:** Voting members will consist of the Chair, the Surgeons General of the Military Services, the Director, Health and Safety of the U. S. Coast Guard, and representatives from the ACIP and the AFEB. Subcommittees, either continuing or ad hoc, shall be established as needed as working groups of the NAB to assist in performing its functions. When necessary, each subcommittee may request the advice of non-voting consultants to provide the requisite balance in viewpoints through breadth of expertise. Representatives to the NAB should include board-certified specialists in the fields of immunology, infectious disease, pediatrics, family medicine, and operational medicine. The membership will include:

Director, DoD National Vaccine Healthcare Center Network	Chair
Member of the Advisory Committee on Immunization Practices	Member
Member of the Advisory Committee on Immunization Practices	Member
Member of the Armed Forces Epidemiological Board	Member
Member of the Armed Forces Epidemiological Board	Member
Representative from the Centers for Disease Control and Prevention	Member
Academic Immunology/Immunization/Vaccine Safety Expert	Member
Academic Immunology/Immunization/Vaccine Safety Expert	Member
Representative , Assistant Secretary for Health, Department of Health and Human Services	Ex-Officio Representative
Representative, Surgeon General of the Army	Ex-Officio Representative
Representative, Surgeon General of the Navy	Ex-Officio Representative
Representative, Surgeon General of the Air Force	Ex-Officio Representative
Representative, Marine Corps Surgeon	Ex-Officio Representative
Representative, Health and Safety of the U. S. Coast Guard	Ex-Officio Representative
Representative. TRICARE Management Activity	Ex-Officio Representative
Representative, Under Secretary for Health Department of Veterans Affairs	Ex-Officio Representative
Executive Secretary	
Staff Assistant	

5. **MEETINGS:** Bi-annual meetings with additional meetings as requested by Chair.

   SUBCOMMITTEES: Continuing or ad hoc subcommittees shall be established as needed. Subcommittees shall be represented on the parent NAB. The chair of the NAB shall appoint voting members and designate one to serve as the chairperson. When necessary, a subcommittee may request the advice of non-voting consultants in order to enable it to carry on its work while providing the requisite balance in viewpoints through breadth of expertise.

6. **SUPPORT AGENCY:** The Surgeon General, Department of the Army shall be responsible for providing administrative and staff support for operation of the NAB through the Walter Reed National Vaccine Healthcare Center Network. Administrative support is defined as budgeting, funding, fiscal control, manpower control and utilization, personnel administration, security administration, space, facilities, supplies and administrative services.

7. **INDIVIDUAL PROCUREMENTS:** The NAB is not authorized to advise on individual procurements. No matter shall be assigned to the NAB for its consideration that would require any member of the NAB or Subcommittees to participate personally and substantially in the conduct of any specific procurement, or place him or her in the position of acting as a "procurement official," as that term is defined pursuant to law.

8. **DELIVERABLES.** Written minutes from meetings to include consensus statements on clinical and research issues brought to the committee.

9. **DURATION OF DOD NATIONAL VACCINE HEALTHCARE CENTER NETWORK CLINICAL ADVISORY BOARD.** The Charter of the DoD National Vaccine Healthcare Center Network Clinical Advisory Board is subject to renewal two (2) years from the date of this charter and every two years thereafter unless abolished by re-issuance or cancellation.

William Winkenwerder Jr., MD

ASD(HA) Approval Date:

Information Paper

DoD National Vaccine Healthcare Center Network

ISSUE

The National Vaccine Healthcare Center Network (VHC) is a collaborative effort between the Department of Defense (DoD) and the Centers for Disease Control and Prevention (CDC) /National Immunization Program (NIP) to provide compliance with HR 4205 by permitting DoD to fulfill the requirements set forth in Section 735 paragraph (d) "system for monitoring adverse reactions of the anthrax vaccine." In addition to providing compliance with existing legislation, the network offers DoD, in collaboration with the CDC, a means to establish an overall system for monitoring adverse events for all vaccines. It also provides a capability for DoD to respond to the rapidly evolving current and future vaccine health care needs.

Current resourcing does not accommodate the needs of the proposed network. Additional manpower requirements are projected for the Allergy-Immunology Department of the Walter Reed Army Medical Center as workload to support this initiative increases.

The Anthrax Vaccination Immunization Program has highlighted areas of improvement in the military vaccination system that must be addressed. These include:

1. Response to servicemembers who express concern that they may have suffered adverse events to vaccinations;
2. Training of immunization supervisory providers, nursing personnel and technicians;
3. Understanding of the Vaccine Adverse Events Reporting System (VAERS) and individual provider responsibilities to submit the VAERS-1 form in cases of adverse events temporally associated with vaccination;
4. Provider understanding of what constitutes an adverse event that occurs with a temporal relationship to a vaccination;
5. In-depth VAERS reporting to include follow-up VAERS on persistent medical problems that adversely impact on quality of life or result in disability;
6. Provider understanding of balanced risk communication (in a high anxiety, low trust environment) in relation to anthrax vaccine specifically and immunizations in general;
7. Policy and resourcing for implementation of quality standards regarding administration of vaccines within the DoD;
8. Medical resources for the diagnosis, treatment and long term follow-up of patients with complex, chronic, multi-system diseases such as chronic fatigue syndrome with onset temporally associated with an anthrax immunization event.

NATIONAL VHC NETWORK VISION

The VHC is a network of regional vaccine health-related clinical programs aimed at facilitating the health care of military members and DoD beneficiaries that involve vaccines and other therapeutic modalities that improve personal immune protection and "immune readiness." The VHC network is dedicated to continuous performance improvement of immunization and immune therapy health care delivery, from education and research to management of adverse

reactions for all DoD beneficiaries. The VHC network will become a strategically located collection of centers of excellence for military vaccine quality care as well as support for enterprise-wide quality improvements in immunization health care delivery in general. As a platform from which to conduct vaccine studies and as the cornerstone for the CDC/DoD partnership to enhance vaccine safety, efficacy, and acceptability, the VHC network has the potential to become a national resource for the validation of vaccine safety and ongoing surveillance of post-marketing vaccine-related adverse events.

VHC NETWORK MISSION STATEMENT

In order to provide this clinical support and leadership for immune readiness, the VHC network will work in partnership with the CDC and other agencies to develop programs that are dedicated to the highest quality and safety of all immunizations and preventive medicine services. This CDC/DoD collaboration is designed to 1) improve the safety and quality of the delivery of vaccines to military personnel and DoD/VA beneficiaries, 2) improve the reporting of vaccine-related adverse events in military personnel and DoD/VA beneficiaries, 3) improve the quality of clinical management and follow-up of beneficiaries who suffer vaccine-related adverse events, 4) improve military personnel level of satisfaction with their vaccine-related health care services, follow-up experiences, and patient advocacy, and 5) improve beneficiary and vaccine provider knowledge, understanding, and acceptance of immunization requirements.

VHC NETWORK COLLABORATIVE GOALS

The VHC Network will assess and enhance:

- The quality of delivery of immunizations to military personnel and DoD beneficiaries.
- The level of reporting vaccine-related adverse events in the military healthcare system.
- Clinical management and follow-up of vaccine related adverse events and the level of patient advocacy provided to military personnel and beneficiaries who suffer vaccine-related adverse events.
- The knowledge, attitudes, and beliefs of military personnel, DoD beneficiaries and providers regarding immunization requirements.
- The number of trained support personnel for immunization health care improvements.

BACKGROUND

Immunizations in general are the cornerstone of "immune readiness" for servicemembers and beneficiaries, both at home and abroad. Immunizations from the beginning have been the most cost-effective disease prevention public health interventions in 20th and 21st century medicine, only exceeded in efficacy by clean water and proper waste disposal. Biological warfare and terrorism are serious threats both within and outside the United States with new and more difficult challenges facing numerous organizations (beside the military) involved in disease and disaster prevention. Even under the worst criticism regarding efficacy, the anthrax vaccination program is a better preventive strategy for the defense against biological warfare and terrorism threats than any other available strategy. A framework for the delivery of multiple immunizations exists throughout the military health care system. However, it has not been standardized or resourced adequately for the many challenges that have developed over the past 15 years.

The entire vaccine world, both within and outside governmental institutions, has been faced with increasing numbers of issues that challenge the credibility and trust in the immunization health care delivery system. The 1990's were a decade of increasing public concern regarding the safety of vaccines in general and distrust of government organizations and the established medical community, particularly in relation to how individuals with adverse reactions to vaccines are cared for and supported. Examples of just some of the issues are summarized below:

- **Live oral polio vaccine.** There have been cases of paralytic polio in previously healthy children caused by this vaccine. As a result, the public's perceptions of risk associated with traditional immunizations in general have steadily increased. The policy of using live oral polio vaccine in infants has changed as a consequence to further reduce risk. The National Vaccine Compensation Act, directed toward childhood vaccine injury compensation, does NOT address adults with vaccine-related morbidity and thereby has failed to engender confidence in vaccine safety for some sectors.
- **Swine "flu" vaccine.** In the 1970's, this vaccine caused neurological disease complications resulting in persistent distrust of the very safe current influenza vaccine.
- **First generation hepatitis B vaccine.** This vaccine was derived from a blood product (plasma) and there was a perceived risk of HIV transmission that was resolved by recombinant vaccine generations of today. There was never any data to support the concerns about transmission risk. New concerns about this vaccine have arisen from hair loss to questions regarding the risk of thimerosal and mercury accumulation.
- **Infant rotavirus vaccine.** This vaccine was recalled one year after FDA licensing due to over 100 cases of bowel obstruction and several deaths linked potentially to the vaccine.
- **Neonatal hepatitis B vaccine.** Policy for this vaccine has been changed recently due to new concerns about thimerosal content and possible mercury morbidity (birth and 2 month visit with multiple vaccines exceeding the EPA levels of safety 0.1 mcg/kg/day). There is no data regarding actual harm caused by the vaccine or thimerosal, but national and international policy has moved to a recommendation to modify all vaccines in regard to preservative content. This may result in higher costs of vaccines and decreased availability, particularly in developing countries.
- **Measles and hepatitis B vaccines.** These vaccines have been the subject of increasing suspicion as etiologic factors in autism, multiple sclerosis, diabetes, autoimmune disease, etc. Clear data is lacking to support the validity of these fears, yet data alone has not been an adequate response to managing the public's concerns.
- **HIV transmission and immunizations.** There continues to be a belief that immunizations contributed to or even caused the HIV epidemic in Africa and other developing countries.

There appears to be a trend nationally of negative perceptions feeding the distrust of vaccines in general. The negative factors challenging public trust in vaccines are occurring at a time when distrust of traditional medicine is also growing and there is an increasing trend toward the public's desire for alternative or complementary medicine. Moreover, there are increasing demands for freedom of individual choice in health care. The response to the anthrax vaccine immunization program partially reflects the background issues surrounding vaccines in general.

The deficiencies of immunization health care within the DoD have been reviewed in a recent report to the Armed Forces Epidemiological Board: **Vaccines in the Military: A DoD-Wide Review of Vaccine Policy and Practice.** A Report for the Armed Forces Epidemiological Board (AFEB), April 1999; AFEB Infectious Disease Control Subcommittee: "Deficiencies of the current approach to the delivery of vaccines in the DoD" (page 72-77). In addition, the National Vaccine Advisory Committee has recently published a subcommittee report on improved standards for quality adult immunization programs in non-traditional sites that challenges all health care systems to address vaccine delivery and resourcing of quality standards implementation. (**Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation.** MMWR 2000;49(RR-1)(Mar 24);1-13. www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4901a1.htm) The existing health care system has not been resourced to meet the complexities and resource requirements of 21st century immunization health care delivery.

In the context of these standards and national concerns, there is a renewed emphasis on vaccine adverse events reporting or the VAERS system — specifically, developing a more visible outreach for quality improvements in VAERS reporting and follow-up. Anthrax is an older vaccine and post marketing surveillance for adverse events is critical to the credibility of the program. Vaccines are prescription drugs. All prescription drugs are associated with adverse reactions or side effects at a minimum rate of one to two percent. Drug-related medical problems, including those associated with vaccines, should be treated proactively, recognizing that causality can frequently not be proven or disproved. This is a part of doing business and trust is built if the resources to care for the problems are available and credible.

STATUS OUTLINE

1. VHC Structure

The VHC Network has one Lead VHC located at Walter Reed Army Medical Center, responsible for the co-ordination and development of policies, tools, education materials and standard operating procedures for all VHC sites, and Regional VHCs. Initial training of Regional VHC personnel will be the responsibility of the Lead VHC. The Lead VHC will co-ordinate its efforts with existing DoD organizations dedicated to quality immunization services within the services and the Veteran's Administration.

The Lead VHC reports to DoD and the CDC. DoD, through the Army as the executive agent, will provide command and control and administrative support of the entire VHC program. The current organizational framework for the VHC network includes the North Atlantic Regional Medical Command (NARMC) as the Regional Command servicing the Lead VHC; the Walter Reed Army Medical Center as the hosting agency for the Lead VHC; and the Allergy-Immunology Department of Walter Reed Army Medical Center as internal subject matter experts. The Lead VHC will report to the DoD through this chain. The Lead VHC reports to the CDC through the National Immunization Program (NIP). Within the NIP there will be a cell of personnel to provide program management and data management to the overall VHC Network program. Future co-ordination with the VA and civilian centers developed for comparable issues will be a developmental requirement.

There are potentially more than 600 DoD immunization sites worldwide in need of support. Categorization of support requirements within each region and for individual sites must first be identified for comprehensive standardization of practice, educational support, assistance with VAERS reporting, and case management of complex adverse events related patients. To support this effort, the number of VHC sites required throughout the DoD potentially exceeds 16. The scope of work and extent of outreach within each region remains to be defined. The regional VHCs are under the command and control of the Lead VHC, and all data collected will be reported through the lead VHC. Personnel for the lead VHC and the first regional VHC are in training. Both the lead VHC and the NARMC VHC are located at WRAMC

FACILITIES

Providing adequate facilities for the VHC mission within DoD facilities requires resourcing of renovations and structural adaptations to accommodate personnel and automation requirements. Since the VHC function is to provide a visible and accessible service center and "safe haven" for vaccine related reporting and problem solving, both for providers and patients, location of the VHC within existing military treatment facilities is essential. Initial renovations for the Lead and NARMC regional VHC was completed in May of 2001. The facilities include a service center, clinical evaluation spaces to include facilities for specialized testing and vaccine dose challenges, and a 16-seat learning laboratory/classroom integrated with the existing TRISERVICE Immunization-Allergy-Asthma Specialist School.

INITIAL PRIORITIES

The initial phase of the VHC initiative, involving the NARMC regional scope, will focus on the development of a core training program for personnel involved (currently 9 weeks, including risk communication and clinical expertise development) with subsequent outreach to immunization sites within the region. The outreach will include assessment of compliance with new quality standards for immunization services and assessment of training and resource requirements to include development of support programs to these sites. Support programs will include but are not limited to the following:

1. Reviewing and/or assisting in the development of standardized operating procedures that incorporate the new quality standards for immunization services and facilitate VAERS reporting of vaccine related adverse events;
2. Developing mechanisms to provide support for case management of patients with prolonged or more severe adverse events temporally associated with anthrax vaccine specifically and military required vaccines in general;
3. Assisting in the development of local educational resources to include annual update training in vaccine related health care issues to include adverse events information;
4. Developing an enhanced communication network in order to allow for bi-directional information exchange relevant to immunization issues; and
5. Establishing systematic surveys for data necessary for identifying needs for improved VAERS and quality immunization services.

The establishment of a template of standard operating procedures (SOPs) for a regional VHC is a core requirement of the first year scope of work for review and maturation in other regional endeavors to include service specific needs. Each region will be permitted the flexibility to tailor its SOPs in order to meet the specific requirements of its provider and patient population. These SOPs must be living documents in order to respond to the changing vaccine scenarios for the future, but should be coordinated within the Lead VHC in order to foster inter-service consistency for immunization health care.

During VHC regional outreach, personnel will actively perform follow-up on patients with anthrax vaccine-related adverse events to include initial evaluations and reporting of persons not previously captured in the VAERS system.

Personnel will participate in surveys of attitudes, knowledge and beliefs among servicemembers, providers and other beneficiary groups regarding anthrax vaccine, specifically, and other vaccines in general. Focus will be placed on the development of communication and education programs that address the needs of the DoD community.

All initiatives will be developed in collaboration with the CDC/NIP and in coordination with existing DoD functions.

SUBJECT: Draft Charter: Vaccine Healthcare Center Network Advisory Board)

COORDINATION

	Concur	Non-concur
Assistant Sec of the Army (M&RA)	_____	_____
Assistant Sec of the Navy (M&RA)	_____	_____
Assistant Sec of the Air Force (M&RA)	_____	_____
Joint Staff Surgeon	_____	_____
Director, Health and Safety, USCG	_____	_____
President, Armed Forces Epidemiology Board	_____	_____

POC: CDR (b)(6) DHSD, Phone: (b)(6) Fax: (b)(6)

2003035-0000006

9

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

February 6, 2003, 9:00 AM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Policy for Use of Force Health Protection Prescription Products

- This memorandum coordinates the draft policy memorandum for the use of force health protection prescription products (prescription use only) at TAB A.

- There is a suspense date of Feb 21, 2003, because this action directly influences current force health protection policy and will be required when pyridostigmine bromine is approved by the Food and Drug Administration for use as a Soman Nerve Agent Pre-treatment.

- When this coordination is completed, the action establishes new policy. This requests review and comment no later than February 21, 2003. My point of contact is (b)(6) at (b)(6) or by e-mail at: (b)(6)

RECOMMENDATION: That the ASD (HA) sign the attached memorandum at TAB A.

COORDINATION: TAB B

Attachments:
As stated

Prepared by: Salvatore M. Cirone, Program Director, Health Science Policy, Health Operations Policy, (703) 575-2679, PCDOCS# 45615, 45616

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

FEB 1 2 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
UNDER SECRETARY OF DEFENSE (POLICY)
GENERAL COUNSEL
DIRECTOR, JOINT STAFF

SUBJECT: Policy for Use of Force Health Protection Prescription Products

Request your coordination by February 21, 2003, on the attached staff package that contains a draft policy memorandum for the use of force health protection prescription products.

My point of contact for this matter is (b)(6) who may be reached at (b)(6) Concurrence may be faxed to (b)(6)

William Winkenwerder, Jr., MD

Attachments:
As stated

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
DASD (C&PP)

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Policy for Use of Force Health Protection Prescription Products

A requirement of the Federal Food, Drug and Cosmetic Act (21 USC 353(b)(1)) is that certain drugs, vaccines and other medical products, because of the need for medical involvement to assure safe and effective use, may only be used under a physician's prescription. This memorandum establishes policy to comply with this statutory requirement in the context of prescription products used for force health protection. This policy establishes three primary requirements: prescription, issuance in accordance with established medical criteria, and record keeping.

Prescription requirement

All Force Health Protection Prescription Products (FHPPP) shall be issued under a prescription. A blanket prescription may be issued by the Assistant Secretary of Defense (Health Affairs) (applicable to any or all components of the Department of Defense (DoD)), the Surgeon General of the Army, Navy, or Air Force (applicable to personnel in or under the command or authority of the Army, Navy, or Air Force, respectively), or the Command Surgeon of a Combatant Command (applicable to persons within a Combatant Commander's area of responsibility). A blanket prescription shall describe:

- The categories of military personnel and other individuals who are required and/or eligible to receive an FHPPP;
- The exclusion criteria for identifying individuals who for medical reasons are not to be required and/or eligible to receive an FHPPP;
- Appropriate dosing information, including start and stop dates or events;
- Any applicable storage, shipment, and maintenance requirements; and
- Any other appropriate requirements or guidance pertaining to proper medical use of the product.

Issuance of prescription product

All FHPPP shall be provided or issued by qualified personnel who have been instructed on the exclusion criteria and other medical guidance applicable to the product.

These personnel shall conduct necessary medical screening and issue FHPPP consistent with such criteria and guidance.

The administration or issuance for self-administration of all FHPPP shall be preceded and/or accompanied by appropriate education to ensure that recipients are aware of the exclusion criteria, dosing information, potential side effects and recommended responses, sources for additional information, and any other information appropriate for the proper use of the product.

Record keeping

The provision or issuance of FHPPP shall be documented in medical records of the personnel or individuals receiving the FHPPP.

Additional requirements

Health care providers shall record serious adverse events in medical records and shall report serious adverse reactions to the Adverse Events Reporting System of the Department of Health and Human Services using FDA MEDWATCH or Vaccine Adverse Event Reporting System procedures and forms.

DoD Directive 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000, applies to the use of investigational new drugs for force health protection.

Definition

In this memorandum, the term "force health protection" means an organized program of healthcare preventive or therapeutic treatment, or preparations for such treatment, designed to meet the actual, anticipated, or potential needs of a group of military personnel in relation to military missions.

William Winkenwerder, Jr., MD

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Deputy Director for Medical Readiness, Joint Staff

Request for Coordination on the Policy for
Use of Force Health Protection Prescription Products

COORDINATION

OGC (DoD)	Mr.	(b)(6)	2/10/03
CoS (HA)	Ms.	(b)(6)	
PDASD (HA)	Mr.		

Policy for Use of Force Health Protection Prescription Products

COORDINATION

	Concur	Non-concur
Secretary of the Army	_____	_____
Secretary of the Navy	_____	_____
Secretary of the Air Force	_____	_____
Director, Joint Staff	_____	_____
USD (P)	_____	_____
OGC	_____	_____
Surgeon General of the Army	_____	_____
Surgeon General of the Navy	_____	_____
Surgeon General of the Air Force	_____	_____
DASD(C&PP)	_____	_____

TRICARE

TRICARE Management Activity

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

ACTION OFFICE DHS DATE 2-14-03 PCDOCS # 45931
(h) 45615

The attached correspondence is returned for the following reason(s):

- [x] Distribution
- [ ] Coordination
- [ ] Revision
- [ ] Correct Signature Block
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2/19
[redacted] (b)(6)
~~Check w/ Anita AOD(HA) if they distrib'd this or if we need to. I think we do.~~
[redacted] (b)(6)

Additional Comments:

Signed response scanned into PCDocs # 45931

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

	Sign	Coord		Sign	Coord
2/12/03 ASD, HA BW	✓		____ Dir, TMA		
____ PDASD, HA					
____ DASD, C&PP			____ CMO		
____ DASD, FHP&R			____ Dir, DHS		
____ DASD, HB&FP			____ CFO		
____ DASD, HPA			____ COO		
			____ Dir, Regional Operations/PEO		
____ ~~CIO, MHS~~			____ Dir, IMT&R		
2/10/03 OGC, DoD		✓	____ OGC, TMA		
____ LA					
____ ~~CoS, HA~~		✓	____ Dir, A&M		
____ Military Assistant			____ CoS, TMA		
____ Dir, PI, HA			____ Dir, PI, TMA		
____ Dir, P&S			____ Dir, Admin		
____ Other (Specify)			____ Other (Specify)		

DMD (SKY) ~~&RAO~~ Date: 2/6/03 DMD (PNT) A Date: 2/10/03

Date Received: 2/5/03 **Suspense Date:** 2/14/03

Subject: Policy for Use of Force Health Protection Prescription Products

PCDOCS #: 45615, 45616 **OSD/P&R #:**

AO: (b)(6) **Office:** FHP&R **Phone #:** (b)(6)

NOTES: Requests coordination by ~~2/14/03~~ 2/21/03. PMD/PNT to do distro when signed. ~~Done~~. Comeback to AO.

2/13/03

to (b)(6) pls.

TNA (b)(6) 2/10/03

Please call (b)(6) for pick up.

(b)(6)

CMAT Control #
2003038-0000001

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-I 200

(10)

HEALTH AFFAIRS

ACTION MEMO

February/, 2003, 6:00 P.M.

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL AND READINESS)

FROM: Dr. William Winkenwerder Jr., Assistant Secretary of Defense (Health Affairs)

SUBJECT: Annual Report to Congress on Separations Resulting From Refusal to Participate in the Anthrax Immunization Program

- Section 75 1 of National Defense Authorization Act for 2001 requires the SECDEF to submit an annual report to Congress on the separations that have resulted from servicemembers who refused to participate in the Anthrax Vaccine Immunization Program (AVIP).
- This year's annual report, due not later than April 1, 2003, must include the number of members separated categorized by military department, grade, and active duty or reserve status.
- TAB A is a draft memorandum requesting the Services provide the required information, which will be compiled and used in the 2003 Separations Report to Congress.

RECOMMENDATION: Sign memorandum at TAB A

COORDINATION: TAB B

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD (b)(6) PCDOCS# 45870

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

MEMORANDUM FOR SECRETARY OF THE ARMY (M&RA)
SECRETARY OF THE NAVY (M&RA)
SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT: Annual Report to Congress on Separations Resulting From Refusal to Participate in the Anthrax Immunization Program

Section 75 1 of the National Defense Authorization Act for 2001 requires the Secretary of Defense to submit an annual report to Congress on service separations that have resulted from members who refused to participate in the Anthrax Vaccination Immunization Program.

This report must include the number of members separated, branch of service, grade, and active duty or reserve status. This report covers the timeframe from January 1, 2002 through December 3 1, 2002.

Thank you for your attention to this matter. Please provide information no later than 12:00 noon, Friday, March 7, 2003, to the ASD (HA) point of contact, CDR (b)(6) at (b)(6).

David SC. Chu

Cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force

TRICARE

TRICARE Management Activity

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

ACTION OFFICE DHS DATE 3-31-03 PCDOCS # 46171
(B) 45870

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- ☐ Provide Original/Supporting Documents
- ☐ Provide SD 391
- ☑ Retain for your Files

Additional Comments:

Signed Response Scanned into PCDocs # 46171

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

	Sign	Coord		Sign	Coord
_____ ASD, HA		✓	_____ Dir, TMA		
_____ PDASD, HA					
_____ DASD, C&PP			_____ CMO		
_____ DASD, FHP&R			_____ Dir, DHS		
_____ DASD, HB&FP			_____ CFO		
_____ DASD, HPA			_____ COO		
			_____ Dir, Regional Operations/PEO		
_____ CIO, MHS			_____ Dir, IMT&R		
2/12/03 OGC, DoD		✓	_____ OGC, TMA		
_____ LA					
_____ CoS, HA		✓	_____ Dir, A&M		
_____ Military Assistant			_____ CoS, TMA		
_____ Dir, PI, HA			_____ Dir, PI, TMA		
_____ Dir, P&S			_____ Dir, Admin		
_____ Other (Specify)			_____ Other (Specify)		

DMD (SKY) ~~[illegible]~~ **Date:** 2/13/03 **DMD (PNT)** [illegible] **Date:** 2/13/03

Date Received: 2/13/03 **Suspense Date:** _____

Subject: Annual Report to Congress on Separations Resulting From Refusal to Participate in the Anthrax Immunization Program

PCDOCS #: 45870 **OSD/P&R #:** _____

AO: CDR (b)(6) **Office:** DHSD **Phone #:** (b)(6)

NOTES:

CMAT Control #
2003044-0000057

(11)

ACTION MEMO

February 14, 2002 1515

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Deputy Assistant Secretary of Defense for Force Health Protection & Readiness

SUBJECT: Vaccine Health Care Center Network Charter (TAB A)

- The Vaccine Healthcare Center (VHC) Network is a collaborative effort between the Department of Defense and the Centers for Disease Control and Prevention that fulfills Section 751 of the National Defense Authorization Act of 2001. This Act instructs the Secretary of Defense to establish guidelines under which service members "may obtain access to a Department of Defense Center of Excellence treatment facility for expedited treatment and follow up" [10USC 1110(2)(b)(3)] as part of establishing "a system for monitoring adverse events of members of the armed forces to the anthrax vaccine" [10USC 1110(2)(b)(1)].

- The network will develop the structure and tools to support a vaccine safety assessment program, from surveillance through enhanced vaccine adverse events reporting to case management of complex adverse events, and standardize clinical and educational programs focusing on healthcare provider and beneficiary understanding of immunizations and vaccine safety. The first of 15 planned regional centers opened in Washington, DC, at Walter Reed Army Medical Center on September 6, 2001. Background is provided at TAB B.

- The Network Advisory Board will provide consultative review of Network programs, tools and research, assistance and direction on Network services to personnel, review and comment on clinical-management issues, protocols and other vaccine-delivery matters, and guidance and recommendations on collaborative efforts.

RECOMMENDATION: Sign proposed charter at TAB A.

COORDINATION: TAB C

Attachments:
As stated

Prepared by: COL [redacted] OASD(HA)/FHP&R, [redacted]

COORDINATIONS

OTSG, Army	_____
OTSG, Navy	_____
OTSG, Air Force	_____
J-4	_____
OGC	_____

CHARTER

DoD National Vaccine Healthcare Center Network Advisory Board

1. **PURPOSE.** The DoD Vaccine Healthcare Center (VHC) Network Advisory Board (NAB) provides consultative expertise for the review of Network mission specific questions and makes recommendations to the Assistant Secretary of Defense for Health Affairs (ASD(HA)). The ASD(HA) shall appoint a Director, DoD National Vaccine Healthcare Center Network to chair the NAB. The NAB provides periodic oversight recommendations regarding the VHC Network program as well as proposed changes in the mission or functions of the VHC Network.

2. **BACKGROUND.** The Vaccine Healthcare Center (VHC) Network is a collaborative effort between the Department of Defense and the Centers for Disease Control and Prevention that fulfills Section 751 of the National Defense Authorization Act of 2001. This Act instructs the Secretary of Defense to establish guidelines under which service members "may obtain access to a Department of Defense Center of Excellence treatment facility for expedited treatment and follow up" [10USC 1110(2)(b)(3)] as part of establishing "a system for monitoring adverse events of members of the armed forces to the anthrax vaccine" [10USC 1110(2)(b)(1)] The network will function as allergy-immunology Centers of Excellence and be accessible to DoD beneficiaries and providers either directly or on a referral basis. As the Network matures, it will develop the structure and tools to support a vaccine safety assessment program, from surveillance through enhanced vaccine adverse events reporting to case management of complex adverse events. The Network will also assist data collection and standardization in support of improvement of the vaccine adverse. Emphasis will be placed on standardization of clinical and educational programs that focus on healthcare provider and beneficiary understanding of immunizations and vaccine safety. Clinical research partnerships will be developed to validate clinical guidelines and support improvements in vaccine healthcare delivery. The first of 15 planned regional centers opened in Washington, DC, at Walter Reed Army Medical Center on September 6, 2001. Historically the DoD has depended on the Armed Forces Epidemiological Board for vaccine advice and guidance as has the DHHS depended on the ACIP. Representation on the NAB by members of both the AFEB and ACIP bring scientific credibility and institutional independence to the oversight and recommendations provided to the ASD(HA) and the Director, National Vaccine Healthcare Center Network.

3. **GOALS.** The VHC Network Advisory Board goals include but are not limited to:
   - To provide consultative review of programs, tools and research developed by the Vaccine Healthcare Center Network.
   - To provide guidance and recommendations on how to best optimize collaborative efforts between government and civilian agencies with the Vaccine Healthcare Center Network.

- To assist and direct the VHC network in providing its services to personnel in order to enhance the use of vaccines, primarily among military populations, particularly in the operational setting.
- To consult, review, and comment on clinical-management issues, protocols, and other vaccine-delivery issues for the VHC network

4. **MEMBERSHIP.** Voting members will consist of the Chair and the Surgeons General of the Military Services and Director, Health and Safety of the U. S. Coast Guard or their representatives, and representatives from the Advisory Committee on Immunization Practices (ACIP) and the Armed Forces Epidemiological Board (AFEB). Subcommittees, either continuing or ad hoc, shall be established as needed as the working groups of the NAB to assist the NAB in the performance of its functions. When necessary, each subcommittee may request the advice of non-voting consultants in order to enable it to carry on its work while providing the requisite balance in viewpoints through breadth of expertise. Representatives to the VAB should include board-certified specialists in each of the fields of immunology, infectious disease, pediatrics, family medicine, and operational medicine. The full membership will include:

Director, DoD National Vaccine Healthcare Center Network	Chair
Member of the Advisory Committee on Immunization Practices	Member
Member of the Advisory Committee on Immunization Practices	Member
Member of the Armed Forces Epidemiological Board	Member
Member of the Armed Forces Epidemiological Board	Member
Representative from the Centers for Disease Control and Prevention	Member
Academic Immunology/Immunization/Vaccine Safety Expert	Member
Academic Immunology/Immunization/Vaccine Safety Expert	Member
Representative , Assistant Secretary for Health, Department of Health and Human Services	Ex-Officio Representative
Representative, Surgeon General of the Army	Ex-Officio Representative
Representative, Surgeon General of the Navy	Ex-Officio Representative
Representative, Surgeon General of the Air Force	Ex-Officio Representative
Representative, Marine Corps Surgeon	Ex-Officio Representative
Representative, Health and Safety of the U. S. Coast Guard	Ex-Officio Representative
Representative. TRICARE Management Activity	Ex-Officio Representative
Representative, Under Secretary for Health Department of Veterans Affairs	Ex-Officio Representative
Executive Secretary	
Staff Assistant	

5. **MEETINGS**. Biannual meetings with additional meetings as requested by Chair.

   SUBCOMMITTEES. Continuing or ad hoc subcommittees shall be established as needed. Subcommittees shall be represented on the parent NAB. The chair of the NAB shall appoint voting members and designate one of them to serve as the chairperson. When necessary, a subcommittee may request the advice of non-voting consultants in order to enable it to carry on its work while providing the requisite balance in viewpoints through breadth of expertise.

6. **SUPPORT AGENCY.** The Surgeon General, Department of the Army shall be responsible for providing administrative and staff support for operation of the NAB through the Walter Reed National Vaccine Healthcare Center Network. Administrative support is defined as budgeting, funding, fiscal control, manpower control and utilization, personnel administration, security administration, space, facilities, supplies and other administrative services.

7. **INDIVIDUAL PROCUREMENTS.** The NAB is not authorized to advise on individual procurements. No matter shall be assigned to the NAB for its consideration that would require any Member of the NAB or Subcommittees to participate personally and substantially in the conduct of any specific procurement or place him or her in the position of acting as a "procurement official," as that term is defined pursuant to law.

8. **DELIVERABLES**. Written minutes from meetings to include consensus statements on clinical and research issues brought to the committee.

9. **DURATION OF VACCINE HEALTHCARE CENTER NETWORK CLINICAL ADVISORY BOARD**. The Charter of the Vaccine Healthcare Center Network Clinical Advisory Board is subject to renewal two (2) years from the date of this charter and every two years thereafter unless abolished by re-issuance or cancellation.

William Winkenwerder, Jr., M.D.
Assistant Secretary of Defense for Health Affairs

ASD(HA) Approval Date:

Information Paper

Subject: National Vaccine HealthCare Center (VHC) Network

Issue

The Vaccine Healthcare Center Network is a collaborative effort between the Department of Defense (DoD) and the Centers for Disease Control and Prevention (CDC)/National Immunization Program (NIP) to provide compliance with HR 4205 by permitting the DoD to fulfill the requirements set forth in Section 735 paragraph (d) "system for monitoring adverse reactions of the anthrax vaccine." In addition to providing compliance with existing legislation, the Network offers the Department, in collaboration with the CDC, a means to establish an overall system for monitoring adverse events for all vaccines. It also provides a capability for the Department to respond to the rapidly evolving current and future vaccine health care needs.

Current resourcing does not accommodate the needs of the proposed network. Additional funding requirements begin with a need of $5.06 M in FY02. Additional manpower requirements are projected for the Allergy-Immunology Department of the Walter Reed Army Medical Center as workload to support this initiative increases.

The Anthrax Vaccination Immunization Program has highlighted areas of improvement in the military vaccination system that must be addressed. These include:

1. Response to service members who express concern that they may have suffered adverse events to vaccinations;
2. Training of immunization supervisory providers, nursing personnel and technicians;
3. Understanding of the Vaccine Adverse Events Reporting System (VAERS) and individual provider responsibilities to submit the VAERS-1 form in cases of adverse events temporally associated with vaccination;
4. Provider understanding of what constitutes an adverse event that occurs with a temporal relationship to a vaccination;
5. In-depth VAERS reporting to include follow-up VAERS on persistent medical problems that adversely impact on quality of life or result in disability.
6. Provider understanding of balanced risk communication (in a high anxiety, low trust environment) in relation to anthrax vaccine specifically and immunizations in general;
7. Policy and resourcing for implementation of quality standards regarding administration of vaccines within the DoD;
8. Medical resources for the diagnosis, treatment and long term follow-up of patients with complex, chronic, multisystem diseases such as chronic fatigue syndrome with onset temporally associated with an anthrax immunization event.

VHC Network Vision

The National Military Vaccine Healthcare Centers, or VHC, is a network of regional vaccine health related clinical programs aimed at facilitating the health care of military members and DoD beneficiaries that involves vaccines and other therapeutic modalities that improve

personal immune protection and "immune readiness." The VHC network is dedicated to continuous performance improvement of immunization and immune therapy health care delivery, from education and research to management of adverse reactions for all DoD beneficiaries. The VHC Network will become a strategically located collection of centers of excellence for military vaccine quality care as well as support for enterprise wide quality improvements in immunization health care delivery in general. As a platform from which to conduct vaccine studies and as the cornerstone for the CDC/DoD partnership to enhance vaccine safety, efficacy, and acceptability, the VHC network has the potential to become a national resource for the validation of vaccine safety and ongoing surveillance of post-marketing vaccine related adverse events.

VHC NETWORK MISSION STATEMENT

In order to provide this clinical support and leadership for immune readiness, the VHC network will work in partnership with the Centers for Disease Control and Prevention and other agencies to develop programs that are dedicated to the highest quality and safety of all immunizations and preventive medicine services. This CDC/DoD Collaboration is designed to 1) improve the safety and quality of the delivery of vaccines to military personnel and DoD/VA beneficiaries, 2) improve the reporting of vaccine related adverse events in military personnel and DoD/VA beneficiaries, 3) improve the quality of clinical management and follow-up of beneficiaries who suffer vaccine related adverse events, 4) improve military personnel level of satisfaction with their vaccine-related health care services, follow-up experiences, and patient advocacy, and 5) improve beneficiary and vaccine provider knowledge, understanding, and acceptance of immunization requirements.

VHC NETWORK COLLABORATIVE GOALS

The VHC Network will assess and enhance

a) The quality of delivery of immunizations to military personnel and DoD beneficiaries.

b) The level of reporting of vaccine related adverse events (VAEs) in the military health care system.

c) Clinical management and follow-up of vaccine related adverse events (VAEs) and the level of patient advocacy provided to military personnel and beneficiaries who suffer vaccine associated adverse events.

d) The knowledge, attitudes, and beliefs of military personnel, DoD beneficiaries and providers regarding immunization requirements.

e) The number of trained support personnel for immunization health care improvements.

Background

Immunizations in general are the cornerstone of "immune readiness" for service members and beneficiaries, both at home and abroad. Immunizations, from cradle to "golden years," are

to support the validity of these fears yet data alone has not been an adequate response to managing the public's concerns.

- **HIV transmission and immunizations.** There continues to be a "belief" that immunizations contributed to or even caused the HIV epidemic in Africa and other developing countries.

There appears to be a trend nationally of negative perceptions feeding the distrust of vaccines in general. The negative factors challenging public trust in vaccines are occurring at a time when distrust of traditional medicine is also growing and there is an increasing trend toward the public's desire for alternative or complementary medicine. Moreover, there are increasing demands for freedom of individual choice in health care. The response to the anthrax vaccine immunization program partially reflects the background issues surrounding vaccines in general.

The current system for vaccine delivery within the DOD is significantly understaffed and under-trained. Due to a prolonged period of downsizing and an overall nursing shortage, there has been a lack of emphasis on quality vaccine delivery to include education, training and manpower value attributed to the service. (A 5-minute prescription refill is valued more by the administrative workload assessors than a 20-40 minute visits for vaccinations and travel medicine issues.) The deficiencies of immunization health care within the DoD have been reviewed in a recent report to the Armed Forces Epidemiological Board: **Vaccines in the Military: A DoD-Wide Review of Vaccine Policy and Practice**. A Report for the Armed Forces Epidemiological Board (AFEB), April 1999; AFEB Infectious Disease Control Subcommittee: "Deficiencies of the current approach to the delivery of vaccines in the DoD" (page 72-77). In addition, the National Vaccine Advisory Committee has recently published a subcommittee report on improved standards for quality adult immunization programs in non-traditional sites that challenges all health care systems to address vaccine delivery and resourcing of quality standards implementation. (**Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation.** MMWR 2000;49(RR-1)(Mar 24);1-13. www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4901a1.htm) The existing health care system has not been resourced to meet the complexities and resource requirements of 21st century immunization health care delivery.

In the context of these standards as well as national concerns, there is a renewed emphasis on vaccine adverse events reporting or the VAERS system. Developing a more visible outreach for quality improvements in VAERS reporting and follow-up has been a growing emphasis. Anthrax is an older vaccine and post marketing surveillance for adverse events is critical to the credibility of the program. Vaccines are prescription drugs. All prescription drugs are associated with adverse reactions or side effects at a minimum rate of 1-2%. Drug related medical problems, including those associated with vaccines, should be treated proactively recognizing that causality can frequently not be proven or disproven. This is a part of doing business and trust is built if the resources to care for the problems are available and credible.

Status Outline:

1. VHC Structure

The VHC Network has one Lead VHC, responsible for the co-ordination and development of policies, tools, education materials and standard operating procedures for all VHC sites, and Regional VHCs. Initial training of Regional VHC personnel will be the responsibility of the Lead VHC. The Lead VHC will co-ordinate its efforts with existing DoD organizations dedicated to quality immunization services within the services and the Veteran's Administration.

The Lead VHC reports to DoD and the CDC. DoD, through the Army as the executive agent, will provide command and control and administrative support of the entire VHC program. The current organizational framework for the VHC Network includes the North Atlantic Regional Medical Command (NARMC) as the Regional Command servicing the Lead VHC, through Walter Reed Army Medical Center as the hosting agency for the Lead VHC, through the Allergy-Immunology Department of Walter Reed Army Medical Center as internal subject matter experts. The Lead VHC will report to the DoD through this chain. The Lead VHC reports to the CDC through the National Immunization Program (NIP). Within the NIP there will be a cell of personnel to provide program management and data management to the overall VHC Network program. Future co-ordination with the VA and civilian centers developed for comparable issues will be a developmental requirement.

There are potentially more than 600 DoD immunization sites worldwide in need of support. Categorization of support requirements within each region and for individual sites must first be identified for comprehensive standardization of practice, educational support, assistance with VAERS reporting, and case management of complex adverse events related patients. To support this effort, the number of VHC sites required throughout the DoD potentially exceeds 16. The scope of work and extent of outreach within each region remains to be defined. The regional VHCs are under the command and control of the Lead VHC, and all data collected will be reported through the lead VHC. Personnel for the lead VHC and the first regional VHC have been hired and are in training. Both the lead VHC and the NARMC VHC are located at WRAMC

Facilities:

Providing adequate facilities for the VHC mission within DoD facilities requires resourcing of renovations and structural adaptations to accommodate personnel and automation requirements. Since the VHC function is to provide a visible and accessible service center and "safe haven" for vaccine related reporting and problem solving, both for providers and service member patients, location of the VHC within existing military treatment facilities is essential. Initial renovations for the Lead and NARMC regional VHC will be completed by May 1, 2001. The facilities include a service center, clinical evaluation spaces to include facilities for specialized testing and vaccine dose challenges, and a 16 seat learning laboratory/classroom integrated with the existing TRISERVICE Immunization-Allergy-Asthma Specialist School.

Initial Priorities:

The initial phase of the VHC initiative, involving the NARMC regional scope, will focus on the development of a core training program for personnel involved (currently 9 weeks, including

risk communication and clinical expertise development) with subsequent outreach to immunization sites within the region. The outreach will include assessment of compliance with new quality standards for immunization services and assessment of training and resource requirements to include development of support programs to these sites. Support programs will include but are not limited to the following:

1. Reviewing and/or assisting in the development of standardized operating procedures that incorporate the new quality standards for immunization services and facilitate VAERS reporting of vaccine related adverse events;
2. Developing mechanisms to provide support for case management of patients with prolonged or more severe adverse events temporally associated with anthrax vaccine specifically and military required vaccines in general.
3. Assisting in the development of local educational resources to include annual update training in vaccine related health care issues to include adverse events information.
4. Development of enhanced communication network in order to allow for bi-directional information exchange relevant to immunization issues.
5. Establishment of systematic surveys for data necessary for identifying needs for improved VAERS and quality immunization services.

The establishment of a template of standard operating procedures (SOPs) for a regional VHC is a core requirement of the first year scope of work for review and maturation in other regional endeavors to include service specific needs. Each region will be permitted the flexibility to tailor its SOPs in order to meet the specific requirements of its provider and patient population. These SOPs must be living documents in order to respond to the changing vaccine scenarios for the future but should be coordinated within the Lead VHC in order to foster inter-service consistency for immunization health care.

During VHC regional outreach, personnel will actively perform follow-up on patients with anthrax vaccine related adverse events to include initial evaluations and reporting of persons not previously captured in the VAERS system.

Personnel will participate in surveys of attitudes, knowledge and beliefs among service members, providers and other beneficiary groups regarding anthrax vaccine, specifically, and other vaccines in general. Focus will be placed on the development of communication/education programs that address the needs of the DoD community.

All initiatives will be developed in collaboration with the CDC/NIP and in coordination with existing DoD functions.

CMAT Control #
2003052-0000002

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

(12)

HEALTH AFFAIRS

ACTION MEMO

February 25, 2003, 10:00 A.M.

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Designation of US Coast Guard's National Strike Force as an Anthrax Vaccine Immunization Program (AVIP) Priority 1 Designated Special Mission Unit.

- Attached at TAB A is a draft memorandum that designates the US Coast Guard's National Strike Force as a Designated Special Mission Unit and therefore an AVIP priority-1 unit under current DoD policy and implementation plans.
- These National Strike Force teams provide critical response and decontamination support to facilities contaminated with anthrax spores. Most notably, this unit deployed and supported the decontamination of the Hart building in Washington, DC in Fall 2001.
- The Under Secretary of Defense (P&R) policy memorandum dated August 6, 2002, gives the ASD (HA) authority to identify other personnel as mission critical and therefore requiring immunization with the anthrax vaccine.
- This request has been coordinated with the AVIP-MILVAX office, giving full concurrence.

RECOMMENDATION: That ASD(HA) sign memo at TAB A.

COORDINATION: TAB B

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD/ODASD(FHP&R), (b)(6) DCDOCS #43306

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR DIRECTOR, THE JOINT STAFF
COMMANDANT OF THE US COAST GUARD

SUBJECT: Designation of US Coast Guard's National Strike Force as an Anthrax Vaccine Immunization Program (AVIP) Priority 1 Designated Special Mission Unit.

REFERENCE: Under Secretary of Defense for Personnel and Readiness Memorandum, "Policy on Administrative Issues Related to the Anthrax Vaccine Immunization Program (AVIP), August 6, 2002."

By direction of the Undersecretary of Defense for Personnel and Readiness, the Assistant Secretary of Defense for Health Affairs may deem additional personnel occupationally at higher risk for exposure to anthrax and their performance essential for mission critical capabilities.

The increasing threat of the use of weapons of mass destruction makes it essential that we have a critical response and decontamination capability like the US Coast Guard's National Strike Force.

As such, the US Coast Guard's National Strike Force is designated as an Anthrax Vaccine Immunization Program (AVIP) Designated Special Mission Unit and subject to priority-1 anthrax immunization plans.

This designation is effective immediately. COL Gaston Randolph, Director of the AVIP-MILVAX Agency is the point of contact for any question on this matter. He can be contacted at (b)(6).

William Winkenwerder Jr. MD

Subject: Designation of US Coast Guard's National Strike Force as an Anthrax Vaccine Immunization Program (AVIP) Priority 1 Designated Special Mission Unit.

COORDINATION

COL Gaston Randolph, US Army
Director, MILVAX-AVIP Agency

20 February 2003

(b)(6)
02/21/2003 08:28 AM

To: (b)(6) OSAGWI@OSAGWI, (b)(6) OSAGWI@OSAGWI
cc:

Subject: FW: AVIP Special Mission Unit designation

(b)(6)

COL Randolph has made some changes to the AVIP Spec Mission Unit package. See attachment below. Please incorporate into final if has not already gone out.

I haven't seen this before.

Thanks,
(b)(6)

---------- Forwarded by (b)(6) on 02/21/2003 08:29 AM ----------

"Randolph, Gaston M COL OTSG" (b)(6) @otsg.amedd.army.mil>
on 02/20/2003 08:49:50 PM

To: (b)(6) @deploymenthealth.osd.mil" (b)(6) @deploymenthealth.osd.mil>
cc:

Subject: FW: AVIP Special Mission Unit designation

I made a couple recommended changes using Word's Tracking Tool. Randy

-----Original Message-----
From: (b)(6) @deploymenthealth.osd.mil
(b)(6) @deploymenthealth.osd.mil]
Sent: Thursday, February 20, 2003 2:46 PM
To: (b)(6) @otsg.amedd.army.mil
Subject: AVIP Special Mission Unit designation

COL,
Here is a rough for the USCG AVIP' Special Mission Unit designation. Please let me know if there are any glaring errors. Our admin folks are checking the "Memorandum for" line. Please let me know if you see any glaring errors. Thanks sir.

V/R,
(b)(6)

(See attached file: AVIP Designated Special Mission Unit 20 Feb 03.doc)

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

February 26, 2003, 2:30

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection and Readiness **//s//02/25/03**

SUBJECT: Designation of U.S. Coast Guard's National Strike Force as an Anthrax Vaccine Immunization Program (AVIP) Priority 1 Designated Special Mission Unit

- Attached at TAB A is a memorandum that designates the U.S. Coast Guard's National Strike Force as a Designated Special Mission Unit and therefore an AVIP priority-1 unit under current DoD policy and implementation plans.

- These National Strike Force teams provide critical response and decontamination support to facilities contaminated with anthrax spores. Most notably, this unit deployed and supported the decontamination of the Hart building in Washington, DC in Fall 2001.

- The Under Secretary of Defense (P&R) policy memorandum dated August 6, 2002, gives the ASD (HA) authority to identify other personnel as mission critical and therefore requiring immunization with the anthrax vaccine.

- This request has been coordinated with the AVIP-MILVAX office, giving full concurrence (TAB B).

RECOMMENDATION: That the ASD (HA) sign memo at TAB A.

COORDINATION: TAB C

+ Joint Staff
MG James Hawkins
Vice Director, Joint Staff
5 Feb 03.

+ Dr. Anna J. Winegar (Dr.)

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD/OASD (FHP&R), (b)(6)
PCDOCS# 46306

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

MAR 1 8 2003

MEMORANDUM FOR DIRECTOR, THE JOINT STAFF
COMMANDANT OF THE U.S. COAST GUARD

SUBJECT: Designation of U.S. Coast Guard's National Strike Force for Anthrax Vaccine Immunization Program (AVIP)

REFERENCE: Deputy Secretary of Defense "Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)," June 28, 2002

The referenced memorandum authorizes inclusion in the AVIP of additional personnel at higher risk of exposure to anthrax based on performance of critical capabilities.

The increasing threat of the use of weapons of mass destruction makes it essential that we have a critical response and decontamination capability like the U.S. Coast Guard's National Strike Force.

Therefore, I approve inclusion of the U.S. Coast Guard's National Strike Force, involving approximately 213 active duty members, in current AVIP implementation. Execution of the AVIP for these personnel is under the authority of the Commandant of the Coast Guard.

This determination is effective immediately. COL Gaston Randolph, Director of the AVIP-MILVAX Agency is the point of contact for any question on this matter. He can be contacted at (703) 681-5101.

William Winkenwerder, Jr., MD

cc:
Surgeon General of the Army

THE JOINT STAFF
WASHINGTON, DC

Reply ZIP Code:
20318-0300

DJSM-0100-03
05 February 2003

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

Subject: Designation of US Coast Guard's National Strike Force as an Anthrax Vaccination Immunization Program (AVIP) Special Mission Unit

1. The US Coast Guard has requested that the members of its National Strike Force be designated as a Special Mission Unit (Priority 1) under the DOD AVIP (enclosure).

2. The Coast Guard has assigned 213 active duty personnel into three National Strike Teams (NSTs) capable of providing critical response and decontamination support to facilities contaminated with anthrax spores. In the past, this unit has deployed and supported activities such as decontamination of the Hart building in Washington, D.C. The Coast Guard has stated that the NSTs will continue to respond to anthrax contamination in the foreseeable future.

3. This request was coordinated with the Army as the executive agency for the DOD Immunization Program for Biological Warfare Defense.

4. I concur in this request and recommend that the USCG National Strike Force be designated as a special mission unit and that all personnel assigned to this unit receive anthrax immunizations based on that priority.

JAMES A. HAWKINS
Major General, USAF
Vice Director, Joint Staff

Enclosure

Copy to:
Commandant, US Coast Guard

U S Department of Transportation
United States Coast Guard

Commandant
United States Coast Guard

2100 Second Street, S W
Washington, DC 20593-0001
Staff Symbol G-WK
Phone (202) 267-1098
Fax (202) 267-4512
Email

6230

DEC 13 2002

MEMORANDUM

TJ BARRETT
Acting

From THOMAS H COLLINS
COMDT (G-C)

Reply to Attn of. G-WK
RADM Joyce Johnson
202-267-1098

To Department of Defense, Joint Staff, ATTN Joint Staff Surgeon

Subj DESIGNATION OF U.S COAST GUARD'S NATIONAL STRIKE FORCE AS AN AVIP SPECIAL MISSION UNIT

Ref (a) COMDTINST M6230 3A, Coast Guard Anthrax Vaccine Immunization Program (AVIP), page 2
(b) CDC document, Antimicrobial Prophylaxis to Prevent Anthrax Among Decontamination/Cleanup workers Responding to an Intentional Distribution of *Bacillus anthracis*, dtd 22 Oct 01

1 I request that the U S Coast Guard's National Strike Force be designated as an AVIP Special Mission Unit As per reference (a), this will mandate anthrax immunization as a priority 1 unit The U S Coast Guard's National Strike Force includes 213 deployable active duty members divided into three different response teams (National Strike Teams (NSTs)). One mission performed in October-December 2001 was to respond to and perform decontamination efforts in areas known to be contaminated with anthrax Under current mission profiles, the NSTs will respond to anthrax contamination sites for the foreseeable future

2 Reference (b) describes the potential for breaches of protection and the contamination of workers using appropriate personal protection equipment Due to this potential for increased exposure during repeated deployments into contaminated anthrax areas, we request Anthrax vaccine to immunize Strike Team members that are at-risk of exposure due to mission requirements Designation as a Special Mission Unit will allow these at-risk military members to receive licensed anthrax vaccine IAW reference (a), thus ensuring maximum protection for our personnel with the potential to be repeatedly exposed to anthrax contaminated sites.

3 It is our intention to utilize only NST members who have been immunized with the anthrax vaccine as our primary responders to anthrax decontamination sites in the future. Currently, only six Strike Team personnel have begun the anthrax vaccine series Immunizing all Strike Team personnel will ensure that we are ready to respond immediately to any future anthrax contamination site Current projections to start most personnel with three doses of vaccine and bring those previously started in the program up-to-date would require 633 doses

4 My Point of Contact for this matter is RADM Joyce M Johnson at (202) 267-1098

#

Designation of US Coast Guard's National Strike Force as an Anthrax Vaccine Immunization Program (AVIP) Priority 1 Designated Special Mission Unit.

COORDINATION

COL Gaston Randolph, US Army	20 February 2003
Director, MILVAX-AVIP Agency	concur
OGC	as revised 3/4/03
DATSD (CBD)	13 Mar

Designation of US Coast Guard's National Strike Force as an Anthrax Vaccine Immunization Program (AVIP) Priority 1 Designated Special Mission Unit.

COORDINATION

COL Gaston Randolph, US Army	20 February 2003
Director, MILVAX-AVIP Agency	concur
OGC	(b)(6)

OS Revised 3/4/03

03/26/03 09:07 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1874
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	
ST. TIME	03/26 09:07
USAGE T	00'21
PGS. SENT	2
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
(703) (b)(6)
Fax: (703)

FACSIMILE TRANSMITTAL SHEET 3/26/03 8:42:42 AM

TO: COMMANDANT ***FROM:*** (b)(6)

ORGANIZATION: U.S. COAST GUARD

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 2

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: DESIGNATION OF US COAST GUARD NATIONAL STRIKE FORCE FOR ANTHRAX VACCINE INMMUNIZATION PROGRAM (AVIP)

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:
Please confirm receipt

03/26/03 09:06 FAX (b)(6) OSAGWI/MR/MD 001

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*** TX REPORT ***
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TRANSMISSION OK

TX/RX NO	1873
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	JOINT STAFF SG
ST. TIME	03/26 09:05
USAGE T	00'44
PGS. SENT	2
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
(703) (b)(6)
Fax: (703

FACSIMILE TRANSMITTAL SHEET 3/26/03 9:03:54 AM

TO: SURGEON GENERAL ***FROM:*** (b)(6)

ORGANIZATION: JOINT STAFF SURGEON

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 2

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: DESIGNATION OF US COAST GUARD NATIONAL STRIKE FORCE FOR ANTHRAX VACCINE INMMUNIZATION PROGRAM (AVIP)

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:
Please confirm reccipt

(b)(6)

Forward to US Embassy Office
FOR AC:
(1) Prepare package w/
response to DJS and
implementing document (if
FAVORABLE, concur).
(2) Coord action w/ MICVAX

Dir. W wants turnaround NLT
20 FEB – based on the date
of the USCG originating
document.

(b)(6)

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

TRICARE
TRICARE Management Activity

ACTION OFFICE OHS DATE 3-20-03 PCDOCS # 45855
(R) 46306

The attached correspondence is returned for the following reason(s):

- ☑ **Distribution** (b)(6) 3/25
- ☐ **Coordination**
- ☐ **Revision**
- ☐ **Correct Signature Block**
- ☐ **Correct Envelope Size**
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- ☐ **Provide Original/Supporting Documents**
- ☐ **Provide SD 391**
- ☑ **Retain for your Files**

fax copy of memo and attachment to Di joint Staff and Commandant Coast Guard — — copy for Delara and Col Adams

(b)(6)

Additional Comments:

Signed response Scanned into PCDocs #45855

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

	Sign	Coord		Sign	Coord
3/4/03 ASD, HA GW	✓		____ Dir, TMA		
____ PDASD, HA					
____ DASD, C&PP			____ CMO		
____ DASD, FHP&R			____ Dir, DHS		
____ DASD, HB&FP			____ CFO		
____ DASD, HPA			____ COO		
			____ Dir, Regional Operations/PEO		
____ CIO, MHS			____ Dir, IMT&R		
3/4/03 OGC, DoD		✓	____ OGC, TMA		
____ LA					
____ CoS, HA		✓	____ Dir, A&M		
____ Military Assistant			____ CoS, TMA		
____ Dir, PI, HA			____ Dir, PI, TMA		
____ Dir, P&S TAB C			____ Dir, Admin		
3/19/03 Other (Specify) Dr. Johnson-Winegar		✓	____ Other (Specify)		

DMD (SKY) ~~GO~~ **Date:** 2/27/03 **DMD (PNT)** A **Date:** 2/27/03

Date Received: 2/26/03 **Suspense Date:** _____

Subject: Designation of US Coast Guard's National Strike Force as an Anthrax Vaccine Immunization Program Priority 1 Designated Special Mission Unit

PCDOCS #: 46306, 46599 **OSD/P&R #:** _____

AO: COR (b)(6) **Office:** DHS **Phone #:** (b)(6)

NOTES:

Please call Anita or Greg
for pick up.
(703) 697-8979

2003058-0000033

46025

13

THE JOINT STAFF
WASHINGTON, DC

Reply ZIP Code
20318-0300

DJSM-0109-03
06 February 2003

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

Subject. Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

1. Recommend approval of AMC's request (Enclosure A) that selected personnel be approved for anthrax immunizations as an exception to policy.

2 Personnel to be vaccinated under the exception would include strategic airlift crews, Ravens (security forces that travel with the aircraft and protect crews while on the ground at foreign airfields) and tactical airlift control elements (TALCEs) -- an estimated 4,250 personnel, including Active and Reserve Component personnel.

3 Service members are expected to deploy to designated higher-threat areas (HTAs) for more than 15 cumulative days in a 12-month period and are at heightened risk of anthrax exposure This request is supported by USCENTCOM, USEUCOM and USTRANSCOM

4. The Army, as the executive agent for the DOD Immunization Program for Biological Warfare Defense, concurred with critical comment (Enclosure B) Although vaccination of personnel who are in an HTA for cumulative deployments of greater than 15 days in a 12-month period was supported, the Army indicated that vaccinations should begin on an individual basis when the individual is first notified of a deployment or deploys into one of the HTAs for the first time

5 While this approach may be feasible for some Active Component personnel, significant advance planning is required to administer vaccinations to Reserve Component personnel Combined with the relatively short notice inherent in many airlift missions, it seems prudent to give the AMC commander discretion to vaccinate these personnel prior to actual notice of a deployment if it is deemed that they have a high probability of being deployed to an HTA. Furthermore, many of these personnel are expected to require smallpox immunizations under the current smallpox vaccination policy, and it will be much simpler logistically to administer both vaccinations at the same time.

6 TALCE personnel are subject to deployment at less than 12 hours notice to austere fields where medical logistic support to conduct vaccinations is often lacking. Therefore, immediate vaccination of those who are deemed to have a high probability of deploying to an HTA should be authorized.

7 Other Active personnel who have deployed to one of the designated HTAs within the past 12 months should also be authorized for immediate vaccination All other personnel should begin vaccinations as soon as they are designated for deployment to an HTA

8. The Joint Staff points of contact for this issue are Lieutenant Colonel [redacted] and Major [redacted]

JAMES A. HAWKINS
Major General, USAF
Vice Director, Joint Staff

Enclosures

Copy to
HQ USAF, Attn Deputy Chief of Staff for Air and Space Operations

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

AFODM 001-03
16 Jan 03

MEMORANDUM FOR DIRECTOR, JOINT STAFF

SUBJECT Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

Request Joint Staff action on the attached Exception to Policy (ETP) request from AMC/SG (Attachment 1) Current DoD policy for requesting ETP for Priority II anthrax vaccinations requires recommendation from Combatant Commander, with final approval from ASD/HA in consultation with the Chairman, Joint Chiefs of Staff (USD/P&R Memo, 6 Aug 02) (Attachment 2)

Current DoD policy for Priority II anthrax vaccination requires personnel to be assigned or deployed to a higher threat area (HTA) greater than 15 consecutive days AMC strategic airlift aircrews, Ravens and Tactical Airlift Control Elements (TALCEs) are not usually in a HTA greater than 15 *consecutive* days, and therefore, are not authorized to receive anthrax vaccine under Priority Group II However, since many of the designated AMC personnel are in a HTA greater than 15 *cumulative* days, their risk for possible anthrax exposure is increased Therefore, request an ETP for AMC strategic airlift aircrews, Ravens and TALCEs (an estimated 4,250 personnel, including AD and ARC personnel) to receive anthrax vaccine now

Air Staff POCs on this issue are Brig Gen Robert Smolen, HQ USAF/XON (DSN (b)(6) e-mail (b)(6) and Col (b)(6) HQ USAF/SGZP (DSN (b)(6) e-mail (b)(6)

Attachments
1 AMC Request for ETP w/ Bulleted Point Paper
2 6 Aug 02 USD/P&R Memo

RONALD E. KEYS, Lt Gen, USAF
Deputy Chief of Staff
Air & Space Operations

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR MOBILITY COMMAND

29 OCT 2002

MEMORANDUM FOR HQ AFMOA/SG

FROM HQ AMC/SG
203 West Losey Street, Suite 1600
Scott AFB IL 62225-5219

SUBJECT Request for Strategic Airlift Mission Exception to Policy Anthrax Vaccine Implementation Plan (AVIP)

1 Strategic air mobility assets routinely transit geographic areas identified as higher threat areas (HTAs) for anthrax, but are not included in the Air Force AVIP plan Due to their unique missions, AMC/SG requests an Exception to Policy, in accordance with Annex B of the Air Force AVIP 2002 Implementation Plan AMC has identified three specific missions for ETPs Tactical Airlift Control Elements (TALCEs), Strategic Airlift Aircrew Members, and Ravens

2 TALCFs, including their associated Global Reach Liaison (GRL) teams, are subject to rapid deployment (less than 12 hours notice) to austere fields in HTAs on average for 45 days TALCEs lack adequate pre-deployment time to provide an initial anthrax vaccination series (i e shots 1, 2 and 3) Additionally, they often lack the medical logistics support necessary to vaccinate in the field due to their far forward laydown Because of their mission criticality and logistical circumstances, TALCEs should be identified as Priority Two personnel

3 Due to the nature of strategic airlift, aircrew members assigned to this mission are unlikely to remain in place for 15 days or longer, but can be reasonably expected to exceed 15 cumulative days in a 12-month period IAW with instructions in Annex B of the Air Force AVIP 2002 plan, request that AMC and AMC gained C-5, C-17 C-141, and special airlift mission (C-32, C-37, C-40) crewmembers be granted an ETP to initiate immediate anthrax vaccination In addition, ETP to vaccinate Security Forces Ravens is also requested Ravens are specially trained security forces that travel with these aircraft and protect them while on the ground at foreign airfields These flyers and security forces should be identified as Priority Two personnel

4 The Command Surgeon, Headquarters Air Mobility Command, estimates the total number of affected personnel as 4,250 Please refer to the attached point paper for further details Should your staff have any questions, my POC is Lt Col (b)(6) DSN (b)(6) or (b)(6)

CHARLES B. GREEN
Brigadier General, USAF, MC, CFS
Command Surgeon

Attachment:
AVIP ETP Point Paper

POINT PAPER

ON

ANTHRAX VACCINE FOR STRATEGIC AIRLIFTERS

- The Air Force AVIP 2002 Implementation Plan directs anthrax vaccination for personnel assigned 15 consecutive days or longer to Higher Threat Areas (HTAs)
  - AVIP Plan specifically identifies vaccination policy for special missions and those assigned to HTAs and deployed as part of AEF buckets
  - AVIP Plan does not address those military personnel frequently transiting HTAs but not residing for ≥ 15 consecutive days – a frequent occurrence for strategic airlifters
  - AVIP Plan Annex B allows MAJCOM to submit Exception to Policy (ETP)
    - Plan specifically suggests strategic airlift personnel be considered for ETP when personnel can be expected to accumulate 15 days in a 12-month period
- C-5, C-17, C-141 and special airlift mission crewmembers routinely fly into the HTAs and are expected to exceed 15 days in a 12-month period It would be appropriate to vaccinate them based on their frequent exposure/rotation through these HTA
- Ravens, security forces accompanying these aircraft, provide aircraft security at off-station airfields, are also expected to exceed 15 days cumulative days in HTAs, and require similar anthrax vaccine protection
- Tactical Airlift Control Elements (TAI CEs) and Global Reach Laydown teams provide initial aerial port, aircraft maintenance, and C2 for strategic airlift at far forward bases
  - Demanding mission has 12-hour deployment notice for 45-day missions
  - Do not have robust medical support, including routine access to vaccinations
  - They are AEF enablers, not tied to an AEF bucket, subject to deployment at any time
- Based on AMC functional inputs, AMC/SG estimates total AMC and AMC-gained personnel included in these proposals to be 4,250
  - Aircrew (1,000 Active Duty/ 2,350 Air Reserve Component), Ravens (250/220), TALCEs (430 all AD)
- Recommendation. Identify Strategic Airlift Aircrew, Ravens, and TALCEs as AVIP priority two personnel for immediate vaccination to adequately protect them prior to deployment

Lt Col [redacted] AMC/SGPA/DSN [redacted] dob/18 Oct 02

HEADQUARTERS DEPARTMENT OF THE ARMY
ASSISTANT DEPUTY TO THE ARMY OPERATIONS DEPUTY
(JOINT AFFAIRS)
OFFICE OF JOINT AND DEFENSE AFFAIRS

03 FEB 2003

ARMY PLANNER DACS-ZD-JDA
Memorandum Number 085-03

MEMORANDUM FOR SECRETARY, JOINT STAFF, ATTN: J-4 (Health Service Support Division), LTC [redacted]

SUBJECT: Exception to Policy for Anthrax Vaccination for Selected AMC Personnel, (SJS 03-00355)

1. Concur only subject to the following critical comment

2. Critical comment We agree that certain personnel of the USAF Air Mobility Command (AMC) may be at increased risk of *Bacillus anthracis* exposure based on cumulative deployments of greater than 15 days in a twelve-month period; however, anthrax vaccinations should not begin to the entire force of 4,250 personnel immediately on approval of this request. Vaccinations should only begin on an individual basis, when that individual is first notified of deployment or deploys into one of the CJCS-designated High Threat Areas (HTA) for the first time Any deviation from this concept will result in a non-concurrence.

Rationale: The alert status of AMC's subject personnel does not justify immediate vaccination Their alert status is no different than other Services' alert forces (e.g., Division Ready Brigades within Army Divisions), which are not being vaccinated. Rather, on notice of actual deployment these forces begin vaccinating if they fall within the other parameters of the DoD Anthrax Vaccine Immunization Program policy.

Further, current DoD contingency AVA requirements, coupled with competing AVA requests from both U S Federal Agencies and foreign nations, constrain DoD's anthrax vaccine supplies until May 03

3 POC is COL [redacted] or MAJ [redacted] at [redacted]

(b)(6)

Colonel, GS
Deputy to the ADCSOPS (JA)

FAX TRANSMITTAL # of pages ▶

To LTC (b)(6)	From Army Planners
Dept/Agency J-4	Phone # (b)(6)
Fax # (b)(6)	Fax #

SUBJECT: Exception to Policy for Priority-2 Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

COORDINATION

		Non-concur	Concur
Director MILVAX-AVIP Agency	COL [redacted]	_____	_____
DATSD(CBD)	Dr. Anna Johnson-Winegar	_____	_____
DUSD (TSP&CP)	(b)(6)	_____	_____

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

February 27, 2003, 4:00 P.M.

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD) Force Health Protection and Readiness

SUBJECT: Request for Coordination on Exception to Policy for Priority-2 Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

- The Director, Joint Staff endorsed a recommendation by the Air Force to vaccinate selected AMC personnel against anthrax as an exception to policy (TAB B).

- This request includes 4,250 personnel, including strategic airlift crews, Ravens (security forces that protect aircraft and aircrews while transiting foreign airfields), and tactical airlift control elements (TALCEs).

- MILVAX is concerned that all personnel will be immediately vaccinated.

RECOMMENDATION: Sign memorandum requesting coordination at TAB A.

COORDINATION: TAB C.

ATTACHMENTS:
As stated

Prepared by: CDR Eugene de Lara, DHSD/ODASD(FHP&R), (703) 578-8497 PCN 085 # 46025, 46420, 46421.

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR DEPUTY UNDER SECRETARY OF DEFENSE (TSP&CP)
DEPUTY TO THE ASSISTANT SECRETARY OF DEFENSE (CBD)

SUBJECT: Exception to Policy for Priority-2 Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

Request coordination no later than COB Friday, February 28, on the attached draft action memo and exception to policy memorandum for selected AMC personnel.

The draft memorandum grants an exception to policy for priority-2 anthrax vaccinations that was requested by the Air Force and endorsed by the Joint Staff for selected Air Mobility Command personnel. These selected mission personnel may be in high risk threat areas for a 15-day cumulative or greater time frame.

If you have any questions regarding this matter, please contact CDR (b)(6) at [redacted]. Please fax your coordination to [redacted].

William Winkenwerder Jr., MD

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR DIRECTOR, THE JOINT STAFF
COMMANDER, AIR MOBILITY COMMAND

SUBJECT: Exception to Policy for Priority-2 Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

REFERENCE: Under Secretary of Defense (Personnel and Readiness) memorandum, "Policy on Administrative Issues Related to the Anthrax Vaccine Immunization Program (AVIP)," August 6, 2002.

In accordance with the above reference, an exception to policy is approved for Tactical Airlift Control Elements (TALCEs), Strategic Airlift Aircrew Members, and Security Forces Ravens. Begin vaccinating strategic airlift crews now, and Raven security and Tactical Airlift Control Element personnel when they receive their first order to a designated high threat area.

Execution of this vaccination program is per previously published clinical and administrative guidelines and consistent with existing Service implementation plans. The Secretary of the Army remains the Executive Agent for the Anthrax Vaccine Immunization Program (AVIP). Questions regarding this matter shall be directed to COL [redacted] Director of the MILVAX-AVIP agency at [redacted].

William Winkenwerder Jr. MD

DMMC Control #
2003065-0000002

(14)

[redacted]
03/06/2003 08:18 AM

To: (b)(6)
cc:

Subject: Fw: Qs and As for Dr. Winkenwerder

[redacted]has this task. Please task appropriately. (b)(

---------- Forwarded by (b)(6) on 03/06/2003 08:21 AM ----------

(b)(6) LTC, OASD(HA)" (b)(6) on
03/04/2003 04:46:09 PM

To:
cc:

Subject: Fw: Qs and As for Dr. Winkenwerder

Can you assist?

LTC (b)(6)
(b)(6)

-----Original Message-----
From: (b)(6)
To: (b)(6)
Sent: Tue Mar 04 15:55:48 2003
Subject: FW: Qs and As for Dr. Winkenwerder

(b)(6) I got an out of office from Terry. Can you help me get these from FHP&R?

-----Original Message-----
From: (b)(6)
Sent: Tuesday, March 04, 2003 3:50 PM
To:

(b)(6)

Cc:

Subject: Qs and As for Dr. Winkenwerder
Importance: High

We are preparing Dr. W for a Senate Armed Services Committee hearing on March 11. Please submit any Qs and As on "hot topics" that he should be aware of. Qs and As should be very brief and a succinct message that he can easily study. Some topics that should have Qs and As are listed below; please add any other items you feel would be beneficial. Please submit 3-5 Qs and As on these and any other topics by close of business on Thursday, March 6.

Thanks,
(b)(6)

Force Health Protection
Deployment Health Assessments
Smallpox Vaccination Program
DoD Role in Homeland Security
Ennvironmental Surveillance

TRICARE For Life
TRICARE Standard Access/Improvements
Uniform Formulary
T-Nex

T-Nex Governance

DoD/VA Stategic Plan
DoD/VA Resource Sharing

Accrual Fund
DHP FY04
FY03 Shortfalls and Possible Supplemental

TMIP

[redacted]
Office of the Assistant Secretary of Defense (Health Affairs)
TRICARE Management Activity
[redacted]

(b)(6)
Project Support Manager
Deployment Health Support Directorate
(b)(6)

[redacted]
03/06/2003 02:46 PM

To: [redacted]
cc:

Subject: Qs and As for Dr. Winkenwerder

Mr. [redacted]

You asked for a few questions and answers on anticipated "hot topics" for next week's testimony. Attached are what we believe are the top four.

Please let me know if you have any questions. Also, Ms. Embrey hasnt' had a chance to see and chop on these. If she has any changes, I'll let you know.

Regards,
[redacted]

Congressional Q&A for [redacted]

[redacted]
Program Director, Public Affairs and Outreach
Deployment Health Support Directorate
[redacted]

1. **Why aren't you following the law? In 1997, Congress directed that DoD implement pre- and post-deployment medical exams to include a blood draw. Why isn't this being done?**

   The Department of Defense's force health protection program meets the requirements set out by Congress. This complete force health protection program includes regular blood-tests, regular physical examinations, annual dental examinations and annual medical record reviews. In addition to maintaining a fit and healthy force, DoD has added pre- and post-deployment health assessments for servicemembers to document their health status and concerns before and after deployments. All of these together ensure the military is providing a world class continuum of care from accession to separation.

2. **If the military experts don't know what caused Gulf War Syndrome in 1991, how can you be sure you're preventing it this time?**

   Safeguarding the health and safety of our military members is one of the Defense Department's highest priorities. The federally funded research program on Gulf War illnesses has demonstrated Gulf War veterans report chronic symptoms at a higher rate than their non-deployed counterparts, but no unique illness or constellation of symptoms have been identified in Gulf War veterans. Scientists have not identified a causal relationship between the exposures known to have occurred in the Gulf and the illnesses or chronic symptoms of veterans of the Gulf War. The Force Health Protection program today is focused on communicating with deploying forces about the protective measures being taken, documenting healthcare provided, and ensuring timely and effective health follow-up on service members returning from combat operations.

   One important lesson we learned from investigating the Gulf War is that we need the information to determine exactly what harmful exposures individual service members may have encountered, and in what dose. We have far better systems in place now to track unit locations, record what is in the environment, maintain medical records, verify individual health before and after deployment, and, in short, to gather as much information as possible to help scientifically discern the effects of service member deployments on their health.

   Finally, we are responding to individual health concerns with caring and understanding. Current post-deployment clinical practice guidelines actually require military doctors to ask patients if they believe their symptoms may be related to a deployment, and to address those concerns with appropriate evaluations.

3. **By most accounts, medical record keeping has been abysmal. What have you done to fix this?**

   Since the Gulf War, policies for medical record keeping have been strengthened to emphasize the importance of accurate medical recordkeeping for deployed individuals, and ensuring that those records are retrievable as part of the individuals' permanent medical records. The protection and preservation of service member health and fitness for mission success is now an essential component of our military doctrine, operational plans and training. The recent introduction in theater of a secure, web-based deployment health surveillance system provides theater medical personnel a common tool

to electronically capture and archive real-time medical encounter data, and near real-time data on diseases and non-battle injuries. This will significantly improve our ability to archive and retrieve, if necessary, important deployment-related health and medical encounter data. Additionally, access to medical records has improved through closer cooperation between the Departments of Defense and Veterans Affairs, and the National Archives and Records Administration.

For the future, DoD will rely on technology to meet many of its medical record keeping challenges. The next-generation Composite Health Care System (CHCS II) will provide DoD with a Computer-based Patient Record (CPR). Personalized medical and other important personnel information will be available on DoD's Common Access Card/Electronic Information Carrier (CAC/EIC), and the Theater Medical Information Program (TMIP) will automatically integrate medical records captured during overseas deployments and military operations into CPRs.

4. **What is the status of your investigation into the Deseret Test Center's Project 112/SHAD program?**

Our extensive review of classified documents has revealed that the Deseret Test Center planned 134 tests of chemical or biological warfare agents or simulants. Sixty two of these tests were never done, 46 were conducted and we are still working to determine the status of 26 tests. We have had medically relevant information declassified from 42 of the conducted tests and have released fact sheets based on this information. We have provided the VA with the names of nearly 6,000 active duty personnel who participated in these tests. We plan to complete our investigation into the testing done by the Deseret Test Center and release all declassified medically relevant information by June of 2003.

DMMC Control #
2003066-0000006

(15)

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

March 6, 2003, 4:00 P.M.

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Request for Exception to Policy for Priority II Anthrax Vaccinations for Selected Air Force Air Mobility Command (AMC) Personnel.

- Per USD(P&R) policy memo, August 6, 2002, a request for exception to policy requires recommendation from the Combatant Commander, with final approval from ASD(HA) in consultation with the Chairman of the Joint Chiefs of Staff.

- The Director, Joint Staff endorsed a recommendation by the Air Force to vaccinate certain AMC personnel against anthrax as an exception to policy (TAB B). This request includes 4,250 personnel, including strategic airlift crews, Ravens, and tactical airlift control elements (TALCEs). For the purpose of determining impact to overall supply, 12,750 doses (4,250 x 3 inoculations) is the planning figure.

- The Joint Staff recommended approval of this request in its entirety; however, the MILVAX-AVIP agency is concerned that all personnel under the requested exception to policy would be immediately vaccinated. They recommend phasing vaccinations to start at the time the person is actually placed on orders to high threat area.

- The Deputy for Chemical and Biological Defense non-concurs with immediately immunizing the entire 4,250 AMC personnel outlined in the request. He recommends vaccinations for these individuals after notification of deployment to a high-risk area.

- Given stockpile concerns, it is reasonable to approve immediate vaccination of strategic airlift crews now, and approve vaccination of Raven and TALCE personnel only when placed on orders to a designated high threat area.

RECOMMENDATION: Approve phased vaccination by signing memo at TAB A.

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR [redacted] DHSD/ODASD(FHP&R), (b)(6) [redacted] 46714, 46715

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

MAR 10 2003

MEMORANDUM FOR DIRECTOR, THE JOINT STAFF
COMMANDER, AIR MOBILITY COMMAND

SUBJECT: Request for Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

REFERENCE: Under Secretary of Defense (Personnel and Readiness) memorandum, "Policy on Administrative Issues Related to the Anthrax Vaccine Immunization Program (AVIP)," August 6, 2002

In accordance with the above reference, an exception to policy is approved for Tactical Airlift Control Elements (TALCEs), Strategic Airlift Aircrew Members, and Security Forces Ravens to be immediately vaccinated against anthrax.

Execution of this vaccination program is per previously published clinical and administrative guidelines and consistent with existing Service implementation plans. The Secretary of the Army remains the Executive Agent for the Anthrax Vaccine Immunization Program (AVIP). Questions regarding this matter shall be directed to COL Gaston Randolph, Director of the MILVAX-AVIP agency. He can be reached at (703) 681-5101.

William Winkenwerder, Jr.

William Winkenwerder, Jr., MD

03/12/03 13:13 FAX (b)(6) OSAGWI/MR/MD 001

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*** TX REPORT ***
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TRANSMISSION OK

TX/RX NO	1778
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	
ST. TIME	03/12 13:12
USAGE T	00'47
PGS. SENT	2
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 3/12/03 1:11:27 PM

TO: ***AMC COMMANER*** ***FROM:***

ORGANIZATION:

FAX NUMBER: ***TOTAL NO. OF PAGES INCLUDING COVER: 2***

PHONE NUMBER: ***SENDER'S PHONE NUMBER:***

SUBJECT: REQUEST FOR EXCEPTION TO POLICY FOR PRIORITY II ANTHRAX VACCINATIONS FOR SELECTED AIR FORCE AIR MOBILITY COMMAND (AMC) PERSONNEL

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

46025

THE JOINT STAFF
WASHINGTON, DC

Reply ZIP Code
20318-0300

DJSM-0109-03
06 February 2003

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

Subject. Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

1. Recommend approval of AMC's request (Enclosure A) that selected personnel be approved for anthrax immunizations as an exception to policy.

2 Personnel to be vaccinated under the exception would include strategic airlift crews, Ravens (security forces that travel with the aircraft and protect crews while on the ground at foreign airfields) and tactical airlift control elements (TALCEs) – an estimated 4,250 personnel, including Active and Reserve Component personnel.

3 Service members are expected to deploy to designated higher-threat areas (HTAs) for more than 15 cumulative days in a 12-month period and are at heightened risk of anthrax exposure This request is supported by USCENTCOM, USEUCOM and USTRANSCOM

4. The Army, as the executive agent for the DOD Immunization Program for Biological Warfare Defense, concurred with critical comment (Enclosure B) Although vaccination of personnel who are in an HTA for cumulative deployments of greater than 15 days in a 12-month period was supported, the Army indicated that vaccinations should begin on an individual basis when the individual is first notified of a deployment or deploys into one of the HTAs for the first time

5 While this approach may be feasible for some Active Component personnel, significant advance planning is required to administer vaccinations to Reserve Component personnel Combined with the relatively short notice inherent in many airlift missions, it seems prudent to give the AMC commander discretion to vaccinate these personnel prior to actual notice of a deployment if it is deemed that they have a high probability of being deployed to an HTA. Furthermore, many of these personnel are expected to require smallpox immunizations under the current smallpox vaccination policy, and it will be much simpler logistically to administer both vaccinations at the same time.

6 TALCE personnel are subject to deployment at less than 12 hours notice to austere fields where medical logistic support to conduct vaccinations is often lacking. Therefore, immediate vaccination of those who are deemed to have a high probability of deploying to an HTA should be authorized.

7 Other Active personnel who have deployed to one of the designated HTAs within the past 12 months should also be authorized for immediate vaccination All other personnel should begin vaccinations as soon as they are designated for deployment to an HTA

8. The Joint Staff points of contact for this issue are Lieutenant Colonel [redacted] and Major [redacted]

JAMES A. HAWKINS
Major General, USAF
Vice Director, Joint Staff

Enclosures

Copy to
HQ USAF, Attn Deputy Chief of Staff for Air and Space Operations

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

AFODM 001-03
16 Jan 03

MEMORANDUM FOR DIRECTOR, JOINT STAFF

SUBJECT Exception to Policy for Priority II Anthrax Vaccinations for Selected AMC Personnel

Request Joint Staff action on the attached Exception to Policy (ETP) request from AMC/SG (Attachment 1) Current DoD policy for requesting ETP for Priority II anthrax vaccinations requires recommendation from Combatant Commander, with final approval from ASD/HA in consultation with the Chairman, Joint Chiefs of Staff (USD/P&R Memo, 6 Aug 02) (Attachment 2)

Current DoD policy for Priority II anthrax vaccination requires personnel to be assigned or deployed to a higher threat area (HTA) greater than 15 consecutive days AMC strategic airlift aircrews, Ravens and Tactical Airlift Control Elements (TALCEs) are not usually in a HTA greater than 15 *consecutive* days, and therefore, are not authorized to receive anthrax vaccine under Priority Group II However, since many of the designated AMC personnel are in a HTA greater than 15 *cumulative* days, their risk for possible anthrax exposure is increased Therefore, request an ETP for AMC strategic airlift aircrews, Ravens and TALCEs (an estimated 4,250 personnel, including AD and ARC personnel) to receive anthrax vaccine now

Air Staff POCs on this issue are Brig Gen Robert Smolen, HQ USAF/XON (DSN (b)(6) e-mail (b)(6) and Col (b)(6) HQ USAF/SGZP (DSN (b)(6) e-mail (b)(6)

Attachments
1 AMC Request for ETP w/ Bulleted Point Paper
2 6 Aug 02 USD/P&R Memo

RONALD E. KEYS, Lt Gen, USAF
Deputy Chief of Staff
Air & Space Operations

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR MOBILITY COMMAND

29 OCT 2002

MEMORANDUM FOR HQ AFMOA/SG

FROM: HQ AMC/SG
203 West Losey Street, Suite 1600
Scott AFB IL 62225-5219

SUBJECT: Request for Strategic Airlift Mission Exception to Policy, Anthrax Vaccine Implementation Plan (AVIP)

1. Strategic air mobility assets routinely transit geographic areas identified as higher threat areas (HTAs) for anthrax, but are not included in the Air Force AVIP plan. Due to their unique missions, AMC/SG requests an Exception to Policy, in accordance with Annex B of the Air Force AVIP 2002 Implementation Plan. AMC has identified three specific missions for ETPs: Tactical Airlift Control Elements (TALCEs), Strategic Airlift Aircrew Members, and Ravens.

2. TALCEs, including their associated Global Reach Liaison (GRL) teams, are subject to rapid deployment (less than 12 hours notice) to austere fields in HTAs on average for 45 days. TALCEs lack adequate pre-deployment time to provide an initial anthrax vaccination series (i.e. shots 1, 2 and 3). Additionally, they often lack the medical logistics support necessary to vaccinate in the field due to their far forward laydown. Because of their mission criticality and logistical circumstances, TALCEs should be identified as Priority Two personnel.

3. Due to the nature of strategic airlift, aircrew members assigned to this mission are unlikely to remain in place for 15 days or longer, but can be reasonably expected to exceed 15 cumulative days in a 12-month period. IAW with instructions in Annex B of the Air Force AVIP 2002 plan, request that AMC and AMC gained C-5, C-17, C-141, and special airlift mission (C-32, C-37, C-40) crewmembers be granted an ETP to initiate immediate anthrax vaccination. In addition, ETP to vaccinate Security Forces Ravens is also requested. Ravens are specially trained security forces that travel with these aircraft and protect them while on the ground at foreign airfields. These flyers and security forces should be identified as Priority Two personnel.

4. The Command Surgeon, Headquarters Air Mobility Command, estimates the total number of affected personnel as 4,250. Please refer to the attached point paper for further details. Should your staff have any questions, my POC is Lt Col (b)(6) DSN (b)(6) or (b)(6)

CHARLES B. GREEN
Brigadier General, USAF, MC, CFS
Command Surgeon

Attachment:
AVIP ETP Point Paper

POINT PAPER

ON

ANTHRAX VACCINE FOR STRATEGIC AIRLIFTERS

- The Air Force AVIP 2002 Implementation Plan directs anthrax vaccination for personnel assigned 15 consecutive days or longer to Higher Threat Areas (HTAs)
  - AVIP Plan specifically identifies vaccination policy for special missions and those assigned to HTAs and deployed as part of AEF buckets
  - AVIP Plan does not address those military personnel frequently transiting HTAs but not residing for ≥ 15 consecutive days – a frequent occurrence for strategic airlifters
  - AVIP Plan Annex B allows MAJCOM to submit Exception to Policy (ETP)
    - Plan specifically suggests strategic airlift personnel be considered for ETP when personnel can be expected to accumulate 15 days in a 12-month period
- C-5, C-17, C-141 and special airlift mission crewmembers routinely fly into the HTAs and are expected to exceed 15 days in a 12-month period It would be appropriate to vaccinate them based on their frequent exposure/rotation through these HTA
- Ravens, security forces accompanying these aircraft, provide aircraft security at off-station airfields, are also expected to exceed 15 days cumulative days in HTAs, and require similar anthrax vaccine protection
- Tactical Airlift Control Elements (TALCEs) and Global Reach Laydown teams provide initial aerial port, aircraft maintenance, and C2 for strategic airlift at far forward bases
  - Demanding mission has 12-hour deployment notice for 45-day missions
  - Do not have robust medical support, including routine access to vaccinations
  - They are AEF enablers, not tied to an AEF bucket, subject to deployment at any time
- Based on AMC functional inputs, AMC/SG estimates total AMC and AMC-gained personnel included in these proposals to be 4,250
  - Aircrew (1,000 Active Duty/ 2,350 Air Reserve Component), Ravens (250/220), TALCEs (430 all AD)
- Recommendation. Identify Strategic Airlift Aircrew, Ravens, and TALCEs as AVIP priority two personnel for immediate vaccination to adequately protect them prior to deployment

Lt Col [redacted] AMC/SGPA/DSN [redacted] dob/18 Oct 02

HEADQUARTERS DEPARTMENT OF THE ARMY
ASSISTANT DEPUTY TO THE ARMY OPERATIONS DEPUTY
(JOINT AFFAIRS)
OFFICE OF JOINT AND DEFENSE AFFAIRS

03 FEB 2003

ARMY PLANNER DACS-ZD-JDA
Memorandum Number 085-03

MEMORANDUM FOR SECRETARY, JOINT STAFF, ATTN: J-4 (Health Service Support Division), LTC [redacted]

SUBJECT: Exception to Policy for Anthrax Vaccination for Selected AMC Personnel. (SJS 03-00355)

1. Concur only subject to the following critical comment

2. Critical comment We agree that certain personnel of the USAF Air Mobility Command (AMC) may be at increased risk of *Bacillus anthracis* exposure based on cumulative deployments of greater than 15 days in a twelve-month period; however, anthrax vaccinations should not begin to the entire force of 4,250 personnel immediately on approval of this request. Vaccinations should only begin on an individual basis, when that individual is first notified of deployment or deploys into one of the CJCS-designated High Threat Areas (HTA) for the first time Any deviation from this concept will result in a non-concurrence.

Rationale: The alert status of AMC's subject personnel does not justify immediate vaccination Their alert status is no different than other Services' alert forces (e.g. Division Ready Brigades within Army Divisions), which are not being vaccinated. Rather, on notice of actual deployment these forces begin vaccinating if they fall within the other parameters of the DoD Anthrax Vaccine Immunization Program policy.

Further, current DoD contingency AVA requirements, coupled with competing AVA requests from both U S Federal Agencies and foreign nations, constrain DoD's anthrax vaccine supplies until May 03

3 POC is COL (b)(6) or MAJ [redacted] at (b)(6)

(b)(6)

Colonel, GS
Deputy to the ADCSOPS (IA)

FAX TRANSMITTAL # of pages ▶
To LTC (b)(6) From Army Planners
Dept / Agency J-4 Phone # (b)(6)
Fax # (b)(6) Fax #

HEADQUARTERS DEPARTMENT OF THE ARMY
Assistant Deputy Chief of Staff for Operations and Plans
(Joint Affairs)

ARMY PLANNER DAMO-ZC
MEMORANDUM NO.

MEMORANDUM FOR SECRETARY, JOINT STAFF, ATTN: J-4 (Health Service Support Division), LTC [redacted]

SUBJECT: Exception to Policy for Anthrax Vaccination for Selected AMC Personnel, Joint Staff Action Number JSJ 03-00355

1. Concur subject to the following critical comment.

2. Critical comment. Concur that subject servicemembers of the US Air Force Air Mobility Command (AMC) may be at increased risk of *Bacillus anthracis* exposure based on cumulative deployments of greater than 15 days in a twelve-month period; however, anthrax vaccinations should not begin to the entire force of 4,250 servicemembers immediately on approval. They should begin in each individual when that individual first is notified of deployment or deploys into one of the CJCS-designated High Threat Areas (HTA) for the first time. Any deviation from this concept will result in a non-concurrence.

Rationale: Although we agree conceptually that subject forces may be at increased risk to exposure, we disagree that vaccinations to all individual servicemembers in the entire subject forces should be started immediately. Rather, the anthrax vaccination 6-dose series should start in each individual only when each individual servicemember in the subject forces has deployment orders into one of the 14 CJCS-designated HTA countries. The alert status of AMC's subject forces should not justify immediate vaccination—their alert status is no different than other Services' alert forces (e.g., Division Ready Brigades within Army Divisions), which are not being vaccinated. Rather, on notice of deployment these forces begin vaccinating if they fall within the other parameters of the DoD Anthrax Vaccine Immunization Program policy.

Further, current DoD contingency AVA requirements, coupled with competing AVA requests from both U.S. Federal Agencies and foreign nations, constrain DoD's anthrax vaccine supplies until May 03.

3. POC is COL [redacted] or MAJ [redacted] at [redacted].

ASSISTANT TO THE SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR AND CHEMICAL
AND BIOLOGICAL DEFENSE
PROGRAMS

MEMORANDUM FOR DEPUTY ASSISTANT SECRETARY OF DEFENSE
FOR FORCE HEALTH PROTECTION AND
READINESS

SUBJECT: Request for Exception to Policy – Anthrax Immunizations for Selected Air Force Air Mobility Command (AMC) Personnel

I cannot concur with your request for exception to policy to immediately immunize 4,250 selected Air Force Air Mobility Command (AMC) personnel. Vaccinations should begin only for individuals who are notified they are to deploy into one of the designated high threat areas and not for all AMC personnel at this time. Anthrax vaccine supplies are very limited and a six shot series for 4,250 personnel requires 25,500 doses of vaccine.

for Steve E Lawrence COL, USA
Anna Johnson-Winegar, Ph.D.
Deputy for Chemical/Biological Defense

Attachments:
As Stated

SUBJECT: Exception to Policy for Priority-2 Anthrax Vaccinations for Selected AMC Personnel

COORDINATION

Director, MILVAX-AVIP Agency	Concur with critical comments
USD (AT&L)	Non-concur with comments
DUSD (TSP&CP)	Concur

[redacted]
03/06/2003 09:50 AM

To: (b)(6)
cc:

Subject: FW: Exception to Policy for Selected AMC Personnel

cc

---------- Forwarded by [redacted] on 03/06/2003 09:53 AM ----------

[redacted] on 03/05/2003 05:15:33 PM

To: (b)(6)

cc:

Subject: FW: Exception to Policy for Selected AMC Personnel

Guys: I spoke at length with the author of this request today. It is prudent to approve this request in its entirety. I made some modifying language. Please review for consistency.

Please process to get thru to Dr W by Friday, 7 Mar. Thanks much.

-----Original Message-----
From: (b)(6)
[mailto:(b)(6)
Sent: Wednesday, March 05, 2003 3:10 PM
To: (b)(6)
Subject: Exception to Policy for Selected AMC Personnel

Sir,
ETP package as discussed.

v/r,
[redacted]

---------- Forwarded by (b)(6) on 03/05/2003 03:12 PM ----------

[redacted]
03/05/2003 03:08 PM

DMMC Control #
2003071-0000008

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

(16)

HEALTH AFFAIRS

ACTION MEMO

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness
(//s// 3-12-03 0915 Colonel Rauch)

SUBJECT: Department of Defense (DoD) Provision of Anthrax Vaccine for Federal Bureau of Investigation (FBI)

- The Assistant Director, Counterterrorism Division of the FBI requested anthrax and smallpox vaccinations to support approximately 150 personnel (TAB B).

- Personnel are integral to the FBI's mission responsible for federal law enforcement crisis response to weapons of mass destruction incidents involving US interests.

- Originally requesting anthrax and smallpox, the FBI was successful in getting smallpox vaccine from Department of Health and Human Services. However, DoD remains the primary source of anthrax vaccine.

- An interagency agreement between DoD and the FBI is required and must be completed before the request can be supported.

- DoD Directive 6205.4, Immunization of Other Than U.S. Forces for Biological Weapons Defense, reserves to the Secretary of Defense the authority to approve the provision of vaccine to non-DoD entities.

RECOMMENDATION: Sign coordination memo at TAB A, DEPSECDEF decision package that authorizes anthrax vaccine to approximately 150 members of the FBI.

COORDINATION: TAB C

Attachment:
As Stated

Prepared by: Colonel [redacted] FHP/R, [redacted] Pedocs 46900

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Department of Defense (DoD) Provision of Anthrax Vaccine for Federal Bureau of Investigation (FBI)

- The Assistant Director, Counterterrorism Division of the FBI requested anthrax and smallpox vaccinations to support approximately 150 personnel (TAB B).

- Personnel are integral to the FBI's mission responsible for federal law enforcement crisis response to weapons of mass destruction incidents involving US interests.

- Originally requesting anthrax and smallpox, the FBI was successful in getting smallpox vaccine from Department of Health and Human Services. However, DoD remains the primary source of anthrax vaccine.

- An interagency agreement between DoD and the FBI is required and must be completed before the request can be supported.

- DoD Directive 6205.4, Immunization of Other Than U.S. Forces for Biological Weapons Defense, reserves to the Secretary of Defense the authority to approve the provision of vaccine to non-DoD entities.

RECOMMENDATION: Sign coordination memo at TAB A, DEPSECDEF decision package that authorizes anthrax vaccine to approximately 150 members of the FBI.

COORDINATION: TAB C

Attachment:
As Stated

Prepared by: Colonel [redacted] FHP/R, [redacted]

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR UNDER SECRETARY OF DEFENSE (POLICY)
UNDER SECRETARY OF DEFENSE (ACQUISITION, TECHNOLOGY, AND LOGISTICS)
UNDER SECRETARY OF DEFENSE (PERSONNEL AND READINESS
GENERAL COUNSEL, DEPARTMENT OF DEFENSE

SUBJECT: Department of Defense (DoD) Provision of Anthrax Vaccine for Federal Bureau of Investigation (FBI)

The Assistant Director, Counterterrorism Division, FBI, requested anthrax vaccination for 150 personnel charged with the mission of national response in the event of an act of biological terrorism. These personnel are integral to the FBI's mission of federal law enforcement crisis response to weapons of mass destruction incidents involving U.S. interests.

Originally requesting anthrax and smallpox, the FBI was successful in getting smallpox vaccine from Department of Health and Human Services. However, DoD remains the primary source of anthrax vaccine.

DoD Directive 6205.4, Immunization of Other Than U.S. Forces for Biological Weapons Defense, reserves to the Secretary of Defense the authority to approve the provision of vaccine to non-DoD entities.

An interagency agreement is required and must be completed before the request can be supported. That interagency agreement is being developed by Office of General Counsel now.

We believe this request merits our support, as the sole source for this vaccine. Request your coordination/comment on the proposed Deputy Secretary of Defense decision package by March 14, 2003. My POC is Colonel [redacted]

William Winkenwerder, Jr., MD

Attachments:
As Stated

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

DepSec Action_____

FOR: DEPUTY SECRETARY OF DEFENSE

FROM: William Winkenwerder, Jr., MD, ASD (Health Affairs)

SUBJECT: Department of Defense (DoD) Provision of Anthrax Vaccine for Federal Bureau of Investigation (FBI)

- The Assistant Director, Counterterrorism Division of the FBI requested anthrax and smallpox vaccinations to support approximately 150 personnel (TAB B).

- Personnel are integral to the FBI's mission responsible for federal law enforcement crisis response to weapons of mass destruction incidents involving U.S. interests.

- Originally requesting anthrax and smallpox, the FBI was successful in getting smallpox vaccine from Department of Health and Human Services. However, DoD remains the primary source of anthrax vaccine.

- An interagency agreement between DoD and the FBI is required and must be completed before the request can be supported.

- DoD Directive 6205.4, Immunization of Other Than U.S. Forces for Biological Weapons Defense, reserves to the Secretary of Defense the authority to approve the provision of vaccine to non-DoD entities.

RECOMMENDATION: Sign memo at TAB A authorizing anthrax vaccine to approximately 150 members of the FBI.

COORDINATION: TAB C

Attachment:
As Stated

Prepared by: Colonel [redacted] FHP/R, [redacted]

DEPUTY SECRETARY OF DEFENSE

1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

MEMORANDUM FOR DIRECTOR, FEDERAL BUREAU OF INVESTIGATIONS

SUBJECT: Request for Anthrax Vaccine

I approve your request for anthrax vaccination of approximately 150 FBI personnel who are assigned national crisis response missions. This approval is subject to the terms of an interagency agreement addressing financial considerations and indemnification.

SUBJECT: Department of Defense (DoD) Provision of Anthrax Vaccine for Federal Bureau of Investigation (FBI)

COORDINATIONS

CoS (HA)	Ms. (b)(6)	_____
PDASD, HA	Mr.	_____
USD(P)	Mr. Douglas J. Feith	_____
USD(AT&L)	Mr. Pete Aldridge	_____
USD(P&R)	Dr. David S.C. Chu	_____
DoD, OGC	Mr.	_____

2003083-0000019

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

(17)

ACTION MEMO

HEALTH AFFAIRS

March 24, 2003,11:30 AM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection and Readiness

SUBJECT: Pentagon Force Protection Agency (PFPA) Request for Priority in the Anthrax Vaccine Immunization Program

- The Pentagon Force Protection Agency requested that its Chemical, Biological, Radiological and Nuclear Directorate (CBRN) personnel receive priority in the Anthrax Vaccine Immunization Program (TAB C).

- The PFPA request included a three-tiered approach to vaccination. Tier 1 consists of approximately 128 employees of the Joint Operations Division (JOD), Hazard Response Division (HRD), and Lab Division (LD). Tiers 2 and 3 consist of administrative and support personnel that have limited potential risk for anthrax exposure inherent in their duties.

- The Joint Staff recommended that tier 1 personnel (128) be given priority for vaccination as an AVIP designated special mission unit (Priority 1). The Joint Staff further recommended that these personnel be provided with smallpox vaccination as an exception to policy. The Joint Staff recommended other tiers NOT be vaccinated at this time (TAB B).

- JOD personnel serve in capacities of liaisons to the response crisis center, building operation control center and incident command, and may have to travel through contaminated areas. The HRD may be tasked to collect concentrated air samples, collecting swabs from suspicious items, and respond to known biological events to ascertain areas of potential contamination. The LD provide hands-on manipulation of routine, suspicious and event-generated biological samples for agent identification.

RECOMMENDATION: ASD (HA) approve request by signing memorandum at TAB A.

COORDINATION: TAB D

Attachments:
As stated

Prepared by: Colonel David Adams, OASD (FHP&R), [redacted] PCDOCS# 47128, 47168, 47345

THE ASSISTANT SECRETARY OF DEFENSE

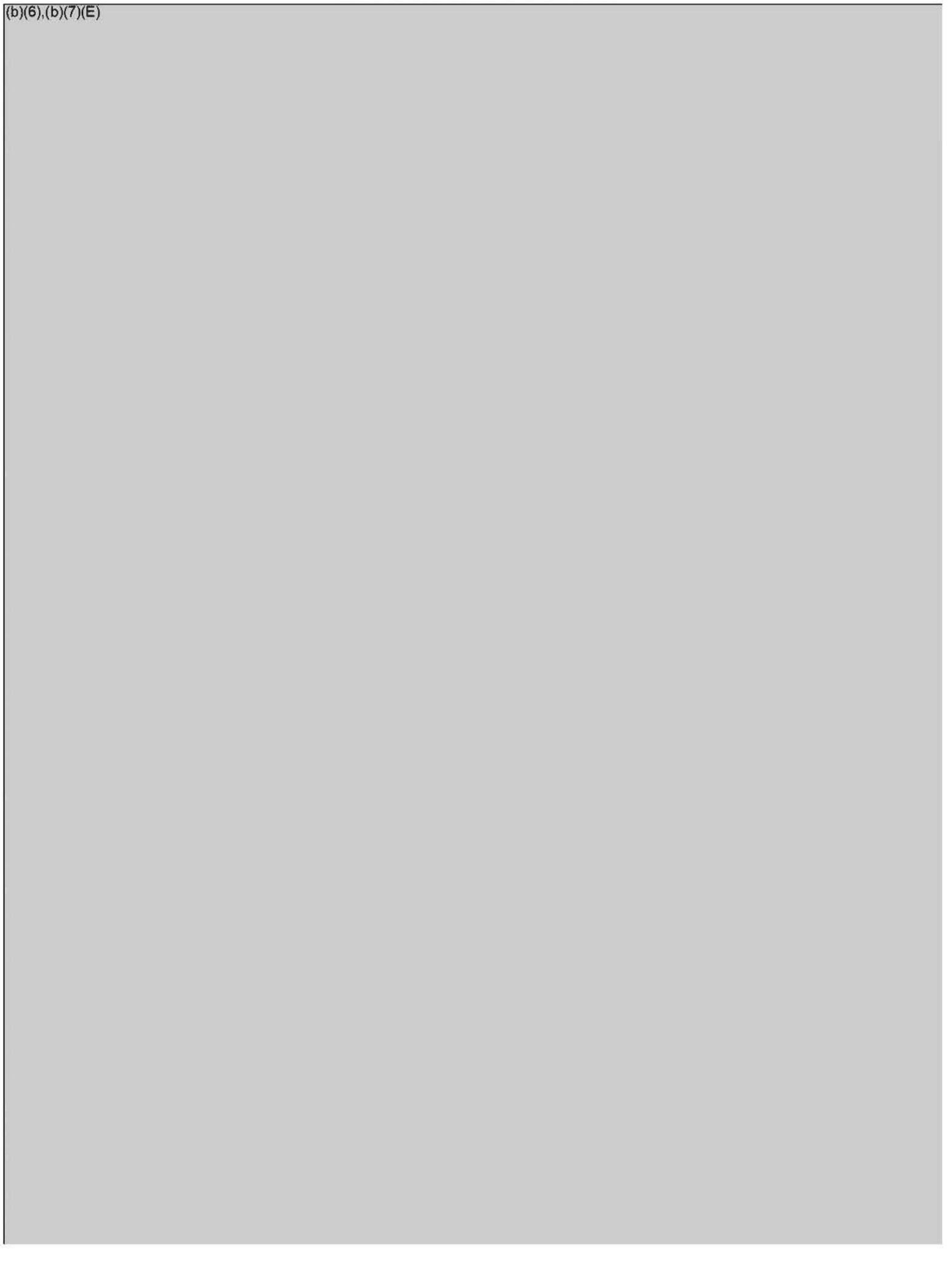
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

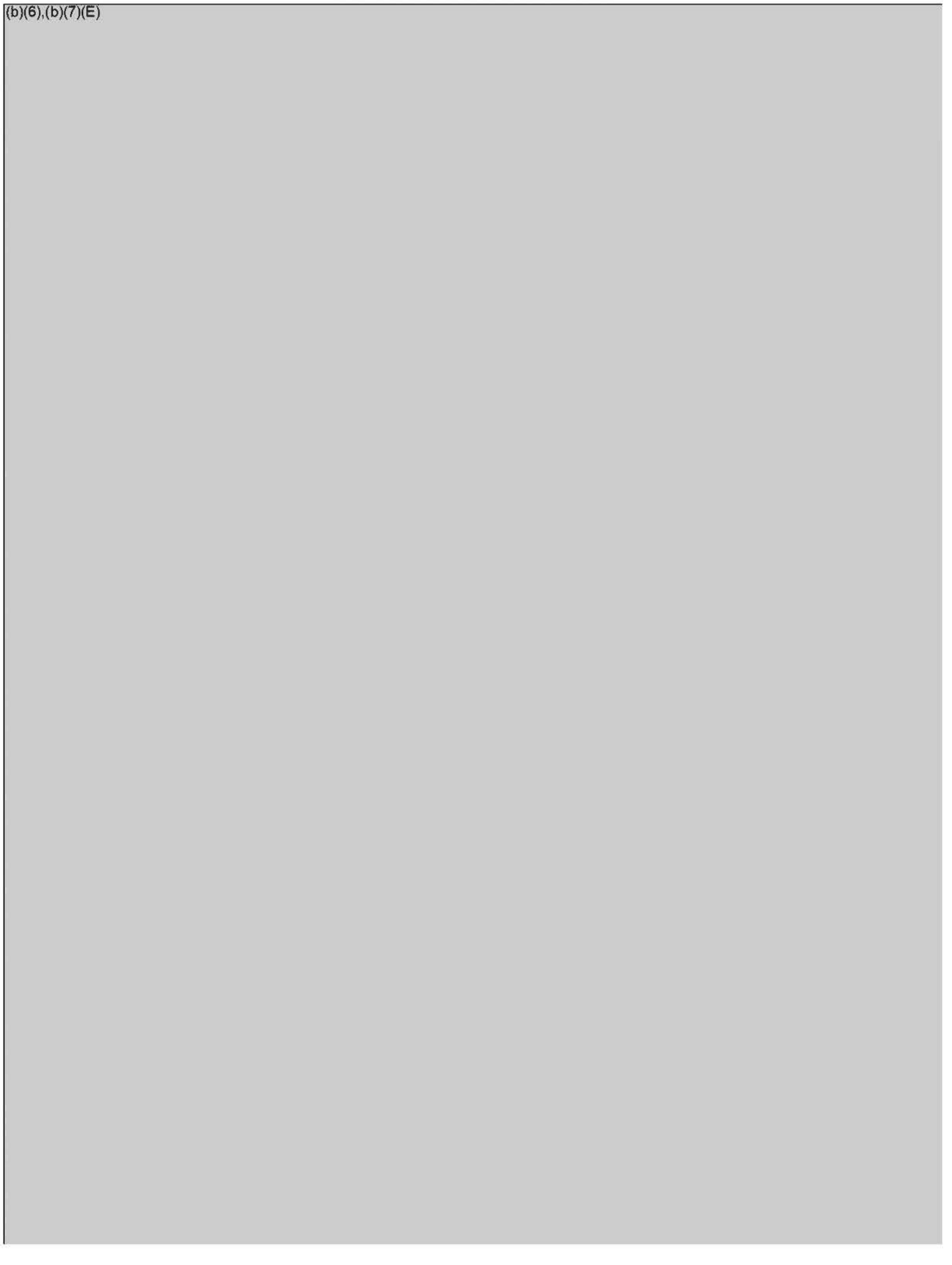
HEALTH AFFAIRS

MEMORANDUM FOR DIRECTOR, JOINT STAFF
DIRECTOR, PENTAGON FORCE PROTECTION AGENCY

I approve your request to vaccinate certain personnel assigned to the Pentagon Force Protection Agency against anthrax and smallpox. Specifically, up to 128 personnel assigned duties in the Joint Operations Division, Hazard Response Division and Lab Division are approved to receive these vaccines. Execution of these vaccination programs are per previously published clinical and administrative guidelines and consistent with existing and approved Service implementation plans.

William Winkenwerder, Jr., MD


(b)(6),(b)(7)(E)


(b)(6),(b)(7)(E)

Coordination: Pentagon Force Protection Agency Request for Priority in the Anthrax Vaccine Immunization Program

DUSD (TSP&CP)	(b)(6)	Concur, 03/21/03
DATSD (CBD)		Concur, 03/21/03
DoD, OGC		_____
CoS, HA		_____
PDASD, HA		_____

Coordination: Pentagon Force Protection Agency Request for Priority in the Anthrax Vaccine Immunization Program

DUSD (TSP&CP)	(b)(6) 21 Mar 03
DATSD (CBD)	
OGC	

Coordination: Pentagon Force Protection Agency Request for Priority in the Anthrax Vaccine Immunization Program

DUSD (TSP&CP)	(b)(6)	
DATSD (CBD)		concur 3/21/03
OGC		

THE JOINT STAFF
WASHINGTON, DC

TAB B

Reply ZIP Code:
20318-0300

DJSM-0218-03
12 March 2003

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

Subject: Pentagon Force Protection Agency Request for Priority in the Anthrax Vaccine Immunization Program

1. The Pentagon Force Protection Agency (PFPA) has requested (Enclosure) that its Chemical, Biological, Radiological and Nuclear (CBRN) Directorate personnel receive priority in the Anthrax Vaccine Immunization Program (AVIP).

2. The PFPA request includes a three-tiered approach to vaccination. Tier 1 consists of approximately 128 employees of the Joint Operations Division, Hazard Response Division, and Lab Division. Tiers 2 and 3 consist of administrative and support personnel that have limited potential risk for anthrax exposure inherent in their duties.

3. Recommend that Tier 1 personnel be given priority for vaccination as an AVIP designated special mission unit (Priority 1). Also recommend that they be provided with smallpox vaccinations as an exception to policy. Approval of vaccinations for Tier 2 and 3 personnel is not recommended.

4. The Joint Staff point of contact for this action is Lieutenant Colonel [redacted]

JAMES A. HAWKINS
Major General, USAF
Vice Director, Joint Staff

Enclosure

Copy to:
Director, Pentagon Force Protection Agency

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301

HEALTH AFFAIRS

to Dr. Winkenwerder
for signature.
- Coordination of
Request for Immunization for
Pentagon Force Protection Agency
operation personnel.

Joint staff recommendation
is at TAB B.

Dtsent.
3/19/03

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301

HEALTH AFFAIRS

I will include DJs request to us. Shares have been in original package. TMA 3/3/03
JA

CAPT Adams —
Either include the JT staff recommendation in the package
— or —
preferably — Coordinate w/ Dirs. JT. Staff.
Pete
Dir T.

TJs to be consistent in all Peer review requests
D 3/7/03

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

March 17, 2003, 3:00 pm

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, Deputy Assistant Secretary of Defense (Force Health Protection and Readiness)

SUBJECT: Pentagon Force Protection Agency (PFPA) Request for Priority in the Anthrax Vaccine Immunization Program

- The Pentagon Force Protection Agency requested that its Chemical, Biological, Radiological and Nuclear Directorate (CBRN) personnel receive priority in the Anthrax Vaccine Immunization Program. (TAB C).

- The PFPA request included a three-tiered approach to vaccination. Tier 1 consists of approximately 128 employees of the Joint Operations Division (JOD), Hazard Response Division (HRD), and Lab Division (LD). Tiers 2 and 3 consist of administrative and support personnel that have limited potential risk for anthrax exposure inherent in their duties.

- The Joint Staff recommended that tier 1 personnel (128) be given priority for vaccination as an AVIP designated special mission unit (Priority 1). The Joint Staff further recommended that these personnel be provided with smallpox vaccination as an exception to policy. The Joint Staff recommended other tiers NOT be vaccinated at this time. (TAB B).

- JOD personnel serve in capacities of liaisons to the response crisis center, building operation control center and incident command, and may have to travel through contaminated areas. The HRD may be tasked to collect concentrated air samples, collecting swabs from suspicious items, and respond to known biological events to ascertain areas of potential contamination. The LD provide hands-on manipulation of routine, suspicious and event-generated biological samples for agent identification.

RECOMMENDATION: ASD (HA) sign the coordination memorandum at TAB A.

COORDINATION: TAB [redacted] D

Attachments:
As stated

Prepared by: Colonel David Adams, OASD (FHP&R), [redacted]

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

MAR 2 0 2003

HEALTH AFFAIRS

MEMORANDUM FOR DEPUTY UNDER SECRETARY OF DEFENSE FOR
TECHNOLOGY SECURITY POLICY AND
COUNTERPROLIFERATION
DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE
FOR CHEMICAL BIOLOGICAL DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE

SUBJECT: Pentagon Force Protection Agency (PFPA) Request for Priority in the Anthrax Vaccine Immunization Program

The Pentagon Force Protection Agency requested that its Chemical, Biological, Radiological and Nuclear (CBRN) Directorate personnel receive priority in the Anthrax Vaccine Immunization Program.

Request your coordination on attached memorandum by COB, Mar 21, 2003.

William Winkenwerder, Jr., MD

Attachments:
As stated

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

March 24, 2003, 11:30 AM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection and Readiness
(//s// 3-24-03 Colonel Rauch)

SUBJECT: Pentagon Force Protection Agency (PFPA) Request for Priority in the Anthrax Vaccine Immunization Program

- The Pentagon Force Protection Agency requested that its Chemical, Biological, Radiological and Nuclear Directorate (CBRN) personnel receive priority in the Anthrax Vaccine Immunization Program (TAB C).

- The PFPA request included a three-tiered approach to vaccination. Tier 1 consists of approximately 128 employees of the Joint Operations Division (JOD), Hazard Response Division (HRD), and Lab Division (LD). Tiers 2 and 3 consist of administrative and support personnel that have limited potential risk for anthrax exposure inherent in their duties.

- The Joint Staff recommended that tier 1 personnel (128) be given priority for vaccination as an AVIP designated special mission unit (Priority 1). The Joint Staff further recommended that these personnel be provided with smallpox vaccination as an exception to policy. The Joint Staff recommended other tiers NOT be vaccinated at this time (TAB B).

- JOD personnel serve in capacities of liaisons to the response crisis center, building operation control center and incident command, and may have to travel through contaminated areas. The HRD may be tasked to collect concentrated air samples, collecting swabs from suspicious items, and respond to known biological events to ascertain areas of potential contamination. The LD provides hands-on manipulation of routine, suspicious and event-generated biological samples for agent identification.

RECOMMENDATION: That the ASD (HA) sign memo at TAB A

COORDINATIONS: TAB D

ATTACHMENTS:
As stated

Prepared by: Col David Adams, OASD (HA)/FHP&R, [redacted] PCDOCS# 47345, 47374

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

MAR 2 6 2003

MEMORANDUM FOR DIRECTOR, JOINT STAFF
DIRECTOR, PENTAGON FORCE PROTECTION AGENCY

I approve your request to vaccinate certain personnel assigned to the Pentagon Force Protection Agency against anthrax and smallpox. Specifically, up to 128 personnel assigned duties in the Joint Operations Division, Hazard Response Division and Lab Division are approved to receive these vaccines. Execution of these vaccination programs shall be consistent with previously published clinical and administrative guidelines, existing and approved Service implementation plans, and, in coordination with the WHS Office of General Counsel, applicable personnel procedures.

William Winkenwerder, Jr., MD

Pentagon Force Protection Agency Request for
Priority in the Anthrax Vaccine Immunization Program

COORDINATION

DUSD (TSP&CP)	(b)(6)	Concur, 03/21/03
DATSD (CBD)		Concur, 03/21/03
DoD, OGC		Concur as revised, 03/21/03
CoS (HA)		_____
PDASD (HA)		_____

Coordination: Pentagon Force Protection Agency Request for Priority in the Anthrax Vaccine Immunization Program

DUSD (TSP&CP) _____

DATSD (CBD) _____

OGC (b)(6), as revised

3/21/03

03/31/03 09:41 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1908
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	
ST. TIME	03/31 09:41
USAGE T	00'38
PGS. SENT	2
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
(b)(6)
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 3/31/03 9:38:50 AM

TO: DIRECTOR, JOINT STAFF ***FROM:*** [redacted]

ORGANIZATION:

FAX NUMBER: [redacted] ***TOTAL NO. OF PAGES INCLUDING COVER:*** 2

PHONE NUMBER: [redacted] ***SENDER'S PHONE NUMBER:*** [redacted]

SUBJECT: REQUEST APPROVAL FOR VACCINATION

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

PLEASE CONFIRM RECIEPT

03/31/03 09:43 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1907	
CONNECTION TEL		(b)(6)
SUBADDRESS		
CONNECTION ID		
ST. TIME	03/31 09:43	
USAGE T	00'21	
PGS. SENT	2	
RESULT	OK	

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
(b)(6)
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 3/31/03 9:37:58 AM

TO: DIRECTOR, PENTAGON FORCE PROTECTION AGENCY ***FROM:***

ORGANIZATION:

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 2

PHONE NUMBER:

SENDER'S PHONE NUMBER:

SUBJECT: REQUEST APPROVAL FOR VACCINATION

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

PLEASE CONFIRM RECIEPT

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

	Sign	Coord		Sign	Coord
3/26 ASD, HA BvO	✓		Dir, TMA		
PDASD, HA					
DASD, C&PP			CMO		
DASD, FHP&R			Dir, DHS		
DASD, HB&FP			CFO		
DASD, HPA			COO		
			Dir, TRICARE Operations/PEO		
CIO, MHS			Dir, IMT&R		
3/21 OGC, DoD		✓	OGC, TMA		
LA					
CoS, HA		✓	Dir, A&M		
Military Assistant			CoS, TMA		
Dir, PI, HA			Dir, PI, TMA		
Dir, P&S			Dir, Admin		
Other (Specify)			Other (Specify)		

DMD (SKY) Date: **DMD (PNT)** A Date: 3/24/03

Date Received: 3/24/03 **Suspense Date:**

Subject: Pentagon Force Protection Agency (PFPA) Request for Priority in the Anthrax Vaccine Immunization Program

PCDOCS #: 47345, 47374 **OSD/P&R #:**

AO: COL Dave Adams **Office:** FHP&R **Phone #:** [redacted]

NOTES: OKs. to Kotto for distro. A 3/24/03

TRICARE

TRICARE Management Activity

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

ACTION OFFICE DHS DATE 3-21-03 PCDOCS # 47374

ATTN:

The attached correspondence is returned for the following reason(s):

- ☑ **Distribution**
- ☐ **Coordination**
- ☐ **Revision**
- ☐ **Correct Signature Block**
- ☐ **Correct Envelope Size**
- ☐ **Correct Letterhead**
- ☐ **Provide Original/Supporting Documents**
- ☐ **Provide SD 391**
- ☑ **Retain for your Files**

Mail it

Additional Comments:

Signed Response Scanned into PCDocs #47374

DMMC Control #
2003085-0000022

(18)

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

MAY 28 2002

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT: Support for an Accelerated Vaccine Planning Effort

REFERENCES: (a) DoD Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," November 26, 1993
(b) DoD Directive 5136.1, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," May 27, 1994
(c) DoD Instruction 6205.2, "Immunization Requirements," October 9, 1986

Action is under way to increase interagency vaccine policy coordination to support development, production, distribution and use of vaccines for protection against biological warfare agents and other threats to public health. Within DoD, the Deputy Secretary of Defense is directing our support. In anticipation of the establishment of a more formal structure, we must immediately accelerate DoD planning and actions necessary to protect against such threats. Our initial efforts will focus on establishing a near-term contingency plan for responding to select disease outbreaks.

In order to accelerate our work, I am, under the authorities of references (a), (b), and (c), establishing a task force with the objective of submitting detailed contingency plans by October 1, 2002, with monthly interim reports to the USD(P&R). There are two immediate actions that require your assistance and support:

1. The Army, as Executive Agent for the DoD Immunization Program for Biological Warfare Defense, will have the lead for supporting the task force. This builds upon the excellent work of the Anthrax Vaccine Immunization Program (AVIP) Agency, which has already taken on broader vaccine program roles.

2. The task force will be established June 11, 2002 to develop detailed contingency plans for addressing select disease outbreaks. This task force will work full-time for four months to produce the required plans. I request that each Military Department identify appropriate military medical experts to participate on this task force. Please nominate one expert for each of the following: clinical medicine, preventive medicine, medical planning, and medical logistics by Monday, June 3, 2002. We will select one individual from each Service for participation in the task force.

This task force will work closely with representatives from the Department of Health and Human Services, and with other representatives from across the federal government. The Deputy Assistant Secretary of Defense (Force Health Protection and Readiness) will oversee the task force and report to me. I plan to work in close collaboration with the Assistant Secretary for Health, Department of Health and Human Services who has expressed a strong interest to establish joint collaboration now. The Under Secretary of Defense (Personnel & Readiness) has asked for an initial report within 4 weeks.

A meeting will be held on June 11, 2002 with the task force to further outline the requirements and expectations. My POC is COL Terry Rauch, [redacted]

William Winkenwerder, Jr., M.D.

cc:
USD(P&R)
USD(AT&L)
JCS (J-4)
Surgeons General
Director, Administration & Management

[redacted] CON, OASD(HA)/TMA

From: (b)(6)
Sent: Friday, May 24, 2002 7:52 AM
To: (b)(6)
Cc:
Subject: RE: Smallpox Task Force

looks okay to me. lets do it

-----Original Message-----
From: (b)(6)
Sent: Thursday, May 23, 2002 1:21 PM
To: (b)(6)
Cc:
Subject: Smallpox Task Force

<< File: Support for Accelerated Vaccine Planning.doc >>

(b)(6)

I have made the suggested changes from OTSG to this memo (except for the ones recommending we establish an expanded AVIP office in this memo).

Pls chop quickly (by 1500) and return to me with an "Ok to sign."

Thanks, [redacted]

[redacted] CON, OASD(HA)/TMA

From: (b)(6)
Sent: Friday, May 24, 2002 8:05 AM
To: (b)(6)
Subject: RE: Smallpox Task Force

(b)(6) Sorry, got behind the power curve yesterday. This looks fine to me and Ms Embrey has also reviewed.

-----Original Message-----
From: (b)(6) OASD(HA)/TMA
Sent: Thursday, May 23, 2002 3:25 PM
To: (b)(6) OASD(HA)
Subject: RE: Smallpox Task Force

(b)(6) -- Any update?

-----Original Message-----
From: (b)(6) OASD(HA)/TMA
Sent: Thursday, May 23, 2002 1:21 PM
To: (b)(6)
Cc:
Subject: Smallpox Task Force

<< File: Support for Accelerated Vaccine Planning.doc >>

(b)(6)

I have made the suggested changes from OTSG to this memo (except for the ones recommending we establish an expanded AVIP office in this memo).

Pls chop quickly (by 1500) and return to me with an "Ok to sign."

Thanks [redacted]

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301

HEALTH AFFAIRS

To Dr. Winkenwerder
for signature.

Ms. Embrey did this
on Friday.
What a task master!

(b)(6)

5/28/02

DMMC Control #
2003105-0000001

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

(19)

ACTION MEMO

April 11, 2003, 10:00 AM

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL & READINESS)

FROM: William Winkenwerder Jr., MD, ASD (Health Affairs)

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

- Attached is a draft supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines under the Department of Defense Voluntary Immunization Program to forward for coordination with the Services, Joint Staff, and appropriate offices (TAB A).
- The policy provides a matrix graphically explaining those categories of personnel, and the locations and circumstances in which they may receive anthrax and/or smallpox vaccinations in accordance with existing Office of the Secretary of Defense policies.
- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: Sign policy memo at TAB A and forward for coordination.

COORDINATION: TAB B

Attachments:
As stated

Prepared by: CDR [redacted] DHSD, [redacted] PCDOCS# 4838

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
DIRECTOR, JOINT STAFF

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

Request your coordination not later than two weeks from the date of this memorandum on the attached draft policy memorandum delineating those categories of personnel, locations, and circumstances in which a person may receive anthrax and/or smallpox vaccinations under the Voluntary Immunization Program.

My point of contact for this matter is CDR [redacted] who may be reached at (b) [redacted] Concurrence may be faxed to [redacted] No response will be taken as concurrence.

William Winkenwerder Jr., MD

Attachments:
As stated

cc:
J-4 (DHS)
Surgeon General, Army
Surgeon General, Navy
Surgeon General, Air Force
Medical Officer, HQ, US Marine Corps
Director of Health and Safety, US Coast Guard

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
GENERAL COUNSEL, DEPARTMENT OF DEFENSE

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

The February 14, 2003, Deputy Secretary of Defense memorandum, Subject: Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions in High-Threat Areas, and the March 13, 2003, Assistant Secretary of Defense (Health Affairs) memorandum, Subject: Clarification of Service Responsibilities in Vaccinating Department of Defense Personnel and Dependents Assigned to Department of State Missions or Residing in High-Threat Areas, directed the Services to provide anthrax and smallpox vaccinations on a voluntary basis to categories of persons in certain overseas' high threat areas. This memorandum provides supplementary administrative guidance for a Voluntary Immunization Program (VIP) with anthrax and smallpox vaccines.

In an effort to support the DoS measures to protect its personnel, and DoD personnel supporting the DoS mission, policies were issued to delineate these efforts. However, other categories of individuals, locations, and circumstances were identified as not being specifically addressed.

Table 1 is a matrix graphically explaining those categories of personnel and the locations and circumstances in which a person may receive anthrax and/or smallpox vaccinations in accordance with the above Office of the Secretary of Defense policies.

Table 1

Personnel Category	Located in DoD HTA	Located in a Non-DoD HTA; but in DoS HTA; assigned to DoS mission	Located in a Non-DoD HTA; but in DoS HTA; not assigned to DoS mission	Conditions:
	Vaccination is:	Vaccination is:	Vaccination is:	
Military	Mandatory	Permitted, Voluntary	Not Permitted	
Adult FM of Military member	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Emergency Essential DoD Civilian (EEC)*	Mandatory	Permitted, Voluntary	Not Permitted	
Non-EEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Adult FM of DoD Civilian (EEC and Non-EEC)	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Mission Essential Contractors (MEC)**	Mandatory	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Non-MEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Adult FM of Contractor (MEC and Non-MEC)	Not Permitted	Not Permitted	Not Permitted	

* DoD civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1999.

** Contractor personnel performing mission essential services as described in DoDI 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," November 6, 1990.

The Services are directed to meet all the same educational, clinical, and administrative requirements to administer vaccinations in these categories of personnel as directed in previous OSD Administrative and Clinical policies for both the DoD Anthrax Vaccine Immunization Program and Smallpox Vaccination Program.

It is essential that individuals receiving the Anthrax and/or Smallpox Vaccines on a voluntary basis be required to complete an Acknowledgement Form prior to receiving any immunization. These forms can be found on DoD's MILVAX website: www.vaccines.army.mil. The signed form must be entered into the individual's medical record.

The Services are directed to document all immunizations: minimally in the individual health records, PHS 731, and preferably in their Service's automated immunization tracking system, as each system's capability allows.

Adverse events in any individual receiving immunizations under the voluntary immunization program should be evaluated at the closest Medical Treatment Facility. Vaccine Adverse Events Reporting System (VAERS) forms should be submitted in accordance with existing Service reporting procedures. VAERS forms are available at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in the implementation of the anthrax and smallpox immunization programs.

David S.C. Chu

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
Assistant Sec of the Army (M&RA)	_____	_____	_____
Assistant Sec of the Navy (M&RA)	_____	_____	_____
Assistant Sec of the Air Force (M&RA)	_____	_____	_____
OSD (OGC)	_____	_____	_____
Dir, Joint Staff	_____	_____	_____

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

DASD, FHP/R	Ms. Ellen P. Embrey	4/14/05
DoD, OGC	(b)(6)	
CoS, HA		
PDASD, HA		

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

April 15, 2003, 2:15 p.m.

FOR: William Winkenwerder Jr., MD, ASD (Health Affairs)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness
//s//4/14/03

SUBJECT: Request for Coordination on Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

- Attached is a draft supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines under the Department of Defense Voluntary Immunization Program to forward for coordination with the Services, Joint Staff, and appropriate offices (TAB B).

- The policy provides a matrix graphically explaining those categories of personnel, and the locations and circumstances in which they may receive anthrax and/or smallpox vaccinations in accordance with existing Office of the Secretary of Defense policies.

- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: That the ASD (HA) sign the memorandum at TAB A

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, (b)(6) PCDOCS# 48381

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

APR 2 2 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
DIRECTOR, JOINT STAFF

SUBJECT: Request for Coordination on Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

Request your coordination not later than two weeks from the date of this memorandum on the attached draft policy memorandum delineating those categories of personnel, locations, and circumstances in which a person may receive anthrax and/or smallpox vaccinations under the Voluntary Immunization Program.

My point of contact for this matter is CDR [redacted] who may be reached at (b)(6 [redacted] Coordination may be faxed to [redacted] No response will be taken as concurrence.

William Winkenwerder, Jr., MD

Attachments:
As stated

cc:
J-4 (DHS)
Surgeon General, Army
Surgeon General, Navy
Surgeon General, Air Force
Medical Officer, HQ, US Marine Corps
Director of Health and Safety, US Coast Guard

DRAFT

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
GENERAL COUNSEL, DEPARTMENT OF DEFENSE

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

The February 14, 2003, Deputy Secretary of Defense memorandum, Subject: Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions in High-Threat Areas, and the March 13, 2003, Assistant Secretary of Defense (Health Affairs) memorandum, Subject: Clarification of Service Responsibilities in Vaccinating Department of Defense Personnel and Dependents Assigned to Department of State Missions or Residing in High-Threat Areas, directed the services to provide anthrax and smallpox vaccinations on a voluntary basis to categories of persons in certain overseas high-threat areas. This memorandum provides supplementary administrative guidance for a Voluntary Immunization Program (VIP) with anthrax and smallpox vaccines.

In an effort to support the DoS measures to protect personnel, and DoD personnel supporting the DoS mission, policies were issued to delineate these efforts. However, other categories of individuals, locations, and circumstances were identified as not being specifically addressed.

Table 1 (attached) is a matrix graphically explaining those categories of personnel and the locations and circumstances in which a person may receive anthrax and/or smallpox vaccinations in accordance with the above Office of the Secretary of Defense (OSD) policies.

The Services are directed to meet all the same educational, clinical, and administrative requirements to administer vaccinations in these categories of personnel as directed in previous OSD administrative and clinical policies for both the DoD Anthrax Vaccine Immunization Program and Smallpox Vaccination Program.

It is essential that individuals receiving the anthrax and/or smallpox vaccines on a voluntary basis be required to complete an acknowledgement form prior to receiving any immunization. These forms can be found on DoD's MILVAX website: www.vaccines.army.mil. The signed form must be entered into the individual's medical record.

The Services are directed to document all immunizations; preferably in their service's automated immunization tracking system, as each system's capability allows. At a minimum, immunizations should be documented in the individual health records, PHS 731.

Adverse events in any individual receiving immunizations under the voluntary immunization program should be evaluated at the closest medical treatment facility. Vaccine Adverse Events Reporting System (VAERS) forms should be submitted in accordance with existing service reporting procedures. VAERS forms are available at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in the implementation of the anthrax and smallpox immunization programs.

David S. C. Chu

Attachment:
As stated

Table 1

Personnel Category	Located in DoD HTA	Located in a Non-DoD HTA; but in DoS HTA; assigned to DoS mission	Located in a Non-DoD HTA; but in DoS HTA; not assigned to DoS mission	Conditions:
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Adult FM of Military member	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
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Non-EEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Adult FM of DoD Civilian (EEC and Non-EEC)	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Mission Essential Contractors (MEC)**	Mandatory	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Non-MEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Adult FM of Contractor (MEC and Non-MEC)	Not Permitted	Not Permitted	Not Permitted	

* DoD civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1999.

** Contractor personnel performing mission essential services as described in DoDI 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," November 6, 1990.

Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

DASD, FHP/R	**Ms. Ellen P. Embrey**	**Concurred 4/14/03**
DoD, OGC	(b)(6)	_____
CoS, HA		_____
PDASD, HA		_____

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

DASD, FHP/R	Ms. Ellen P. Embrey	EPE 4/14/03
DoD, OGC	(b)(6)	
CoS, HA		
PDASD, HA		

TRICARE

TRICARE Management Activity

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

ACTION OFFICE DHS DATE 4-22-03 PCDOCS # 48741

ATTN: CDR de LARA (A) 48381

The attached correspondence is returned for the following reason(s):

- ☐ **Distribution**
- ☐ **Coordination**
- ☐ **Revision**
- ☐ **Correct Signature Block**
- ☐ **Correct Envelope Size**
- ☐ **Correct Letterhead**
- ☐ **Provide Original/Supporting Documents**
- ☐ **Provide SD 391**
- ☐ **Retain for your Files**

Additional Comments:

Signed Response Scanned into PCDocs # 48741

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

	Sign	Coord		Sign	Coord
4/22 ASD, HA	✓	✓	____ Dir, TMA		
____ PDASD, HA					
____ DASD, C&PP			____ CMO		
4/14 DASD, FHP&R		✓	____ Dir, DHS		
____ DASD, HB&FP			____ CFO		
____ DASD, HPA			____ COO		
			____ Dir, Regional Operations/PEO		
____ CIO, MHS			____ Dir, IMT&R		
____ OGC, DoD			____ OGC, TMA		
____ LA					
4/16/03 CoS, HA	✓		____ Dir, A&M		
____ Military Assistant			____ CoS, TMA		
____ Dir, PI, HA			____ Dir, PI, TMA		
____ Dir, P&S			____ Dir, Admin		
____ Other (Specify)			____ Other (Specify)		
DMD (SKY)____ Date:____			DMD (PNT) A Date: 4/16/03		

Date Received: 4/15/03 **Suspense Date:** N/A

Subject: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under DOD Voluntary Immunizatio Program

PCDOCS #: 48381, 48741 **OSD/P&R #:**

AO: ADR (b)(6) **Office:** DHS **Phone #:** (b)(6)

NOTES:

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2118
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USA MRA
ST. TIME	04/30 14:59
USAGE T	01'11
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:59:04 PM

TO: HONORABLE PATRICK HENRY ***FROM:*** [redacted]

ORGANIZATION: ASA (M&RA)

FAX NUMBER: [redacted] ***TOTAL NO. OF PAGES INCLUDING COVER:*** 5

PHONE NUMBER: [redacted] ***SENDER'S PHONE NUMBER:*** [redacted]

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:02 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2119
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USN MRA
ST. TIME	04/30 15:00
USAGE T	01'20
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:59:04 PM

TO: HONORABLE WILLIAM NAVAS, JR ***FROM:***

ORGANIZATION: ASN (M&RA)

FAX NUMBER: [redacted]

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: [redacted]

SENDER'S PHONE NUMBER: [redacted]

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:04 FAX (b)(6) OSAGWI/MR/MD 001

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*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2120
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USAF MRA
ST. TIME	04/30 15:03
USAGE T	00'46
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:59:04 PM

TO: HONORABLE MICHAEL DOMINGUEZ ***FROM:***

ORGANIZATION: ASAF (M&RA)

FAX NUMBER: (b)(6)

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: (b)(6)

SENDER'S PHONE NUMBER: (b)(6)

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:05 FAX (b)(6) OSAGWI/MR/MD 001

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*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2121	
CONNECTION TEL		(b)(6)
SUBADDRESS		
CONNECTION ID		
ST. TIME	04/30 15:04	
USAGE T	00'43	
PGS. SENT	5	
RESULT	OK	

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:52:06 PM

TO:	FROM:
ORGANIZATION: GENERAL COUNSEL	
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER: 5
PHONE NUMBER:	SENDER'S PHONE NUMBER:

SUBJECT: *REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM*

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

04/30/03 15:07 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2122
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	
ST. TIME	04/30 15:05
USAGE T	01'32
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:52:30 PM

TO: DIRECTOR ***FROM:*** (b)(6)

ORGANIZATION: DIRECTOR, JOINT STAFF

FAX NUMBER: [redacted] ***TOTAL NO. OF PAGES INCLUDING COVER:*** 5

PHONE NUMBER: [redacted] ***SENDER'S PHONE NUMBER:*** [redacted]

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:15 FAX (b)(6) OSAGWI/MR/MD 001

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*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2127
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	JOINT STAFF SG
ST. TIME	04/30 15:13
USAGE T	01'33
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: **SURGEON GENERAL** FROM: [redacted]

ORGANIZATION: JOINT STAFF SURGEON

FAX NUMBER: [redacted]

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: [redacted]

SENDER'S PHONE NUMBER: [redacted]

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Please confirm receipt

04/30/03 15:13 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2128
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	J HAMRE
ST. TIME	04/30 15:12
USAGE T	00'45
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: SURGEON GENERAL ***FROM:***

ORGANIZATION: JOINT STAFF SURGEON

FAX NUMBER: ***TOTAL NO. OF PAGES INCLUDING COVER:*** 5

PHONE NUMBER: ***SENDER'S PHONE NUMBER:***

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Please confirm receipt

04/30/03 15:08 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2123
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USA-SG.Rev
ST. TIME	04/30 15:07
USAGE T	00'46
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: **SURGEON GENERAL** FROM: [redacted]

ORGANIZATION: SURGEON GENERAL OF THE ARMY

FAX NUMBER: [redacted]

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: [redacted]

SENDER'S PHONE NUMBER: [redacted]

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:10 FAX (b)(6) OSAGWI/MR/MD 001

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*** TX REPORT ***
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TRANSMISSION OK

TX/RX NO	2124
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	NAVY SG
ST. TIME	04/30 15:09
USAGE T	00'43
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: SURGEON GENERAL **FROM:** [redacted]

ORGANIZATION: SURGEON GENERAL OF THE NAVY

FAX NUMBER: [redacted]

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER: [redacted]

SENDER'S PHONE NUMBER: [redacted]

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2125
CONNECTION TEL	(b)(6)
SUBADDRESS	
CONNECTION ID	USAF SG
ST. TIME	04/30 15:10
USAGE T	01'12
PGS. SENT	5
RESULT	OK

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax: (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:53:33 PM

TO: SURGEON GENERAL ***FROM:***

ORGANIZATION: SURGEON GENERAL OF THE AIR FORCE

FAX NUMBER:

TOTAL NO. OF PAGES INCLUDING COVER: 5

PHONE NUMBER:

SENDER'S PHONE NUMBER:

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

04/30/03 15:16 FAX (b)(6) OSAGWI/MR/MD 001

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2128	
CONNECTION TEL		(b)(6)
SUBADDRESS		
CONNECTION ID		
ST. TIME	04/30 15:15	
USAGE T	00'43	
PGS. SENT	5	
RESULT	OK	

Deployments Health Support Directorate
5113 Leesburg Pike, Suite 901
Falls Church, Virginia 22041
Fax (b)(6)

FACSIMILE TRANSMITTAL SHEET 4/30/03 3:54:32 PM

TO:	*FROM:* [redacted]
ORGANIZATION: U.S. COAST GUARD	
FAX NUMBER: [redacted]	***TOTAL NO. OF PAGES INCLUDING COVER:*** 5
PHONE NUMBER: [redacted]	***SENDER'S PHONE NUMBER:*** [redacted]

SUBJECT: REQUEST FOR COORDINATION ON SUPPLEMENTAL ADMINISTRATIVE POLICY GUIDANCE FOR INDIVIDUALS RECEIVING ANTHRAX AND SMALLPOX VACCINES UNDER A DEPARTMENT OF DEFENSE VOLUNTARY IMMUNIZATION PROGRAM

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

DMMC Control #
2003113-0000003

(20)

APR 29 2002

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (SAF/MI)
CHAIRMAN, JOINT CHIEFS OF STAFF
EXECUTIVE DIRECTOR, TRICARE MANAGEMENT ACTIVITY

SUBJECT: Vaccination of New Recruits Against Hepatitis B

In the 2002 DoD Appropriations Conference Report, Congress requested DoD to begin vaccinating all new recruits against Hepatitis B, to be funded through a "carve out" of $8.4 million from the 2002 appropriations to begin the vaccination program.

In response to this Congressional request, I direct the Services to plan and implement a vaccination program to vaccinate all new recruits. Current DoD policy requires that all health care personnel, Army personnel assigned to Korea, and military personnel traveling to high-risk areas of the world, be immunized against hepatitis B. The Centers for Disease Control and Prevention's Advisory Committee on Immunizations Practices recommends that all health care workers and all infants be vaccinated against hepatitis B, and a catch-up program to immunize older children be instituted as feasible. In addition, adolescents with high-risk factors should be immunized. Many states have required vaccination against hepatitis B as a requirement for school or childcare entry. As a result, the Services should consider serologic testing as part of the immunization program if it is cost beneficial. The Services should submit their implementation plans to this office within 30 days. The vaccination programs should be implemented NLT July 1, 2002.

Attached are vaccination program cost estimates that may be useful to the Services in developing and implementing Service-specific programs.

Because current funding is for FY 02, the Services should submit requirements for the program for FY 03, and include program-specific funding requirements in the FY 04-09 POM submission. Please note that preliminary program estimates far exceed the initial $8.4 million "carve-out."

E. P. Wyatt
for William Winkenwerder, Jr., MD

Attachment:
As stated

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
USMB
USCG

Hepatitis B Vaccination Policy US Army
D
Strategy

WRAIR Prev Med
LTC (b)(6)
(b)(6)

1-Mar-02

1. Serologic screen

Year	2002	2003	2004	2005	2006	5 YR Total
Accessions	257190	257190	257190	257190	257190	1285950
Cost Titers	$2,571,900	$2,700,495	$2,829,090	$2,957,685	$3,086,280	$14,145,450
% Vaccinated	6%	10%	19%	37%	50%	
Non-immune	241759	231471	208324	162030	128595	972178
Cost Vaccinate	$17,164,861	$17,256,163	$16,270,097	$13,229,725	$10,956,294	$74,877,139
Total Cost	$19,736,761	$19,956,658	$19,099,187	$16,187,410	$14,042,574	$89,022,589

2. Universal vaccination

	2002	2003	2004	2005	2006	5 YR Total
Accessions	257190	257190	257190	257190	257190	1285950
Total Cost	$18,260,490	$19,173,515	$20,086,539	$20,999,564	$21,912,588	$100,432,695

3. Vaccinate those not vaccinated as a child

	2002	2003	2004	2005	2006	5 YR Total
Number	241759	231471	208324	162030	128595	972178
Total cost	$17,164,861	$17,256,163	$16,270,097	$13,229,725	$10,956,294	$74,877,139

Includes 5% amortization of the cost of titer and vaccine
Assumes cost of 3 dose vaccine at $71 and titer at $10
Assumes constant accession number per year and age/home state distribution from 2002 to 2006

PCDOC: 34416
SUBJECT: Vaccination of Recruits Against Hepatitis B

COORDINATIONS

DASD (C&PP):	Dr. David Tornberg	3/19/02
HB&FP:	Mr. (b)(6)	3/27/02
CoS,HA	Ms.	
PDASD	Mr.	EMW 4/26
OGC	Mr.	JC 4/18/02 as revised

COORDINATION PAGE

CoS (HA):

C&PP: 3/19/02

HB&FP: 3/27/02

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

March 21, 2002, 3:00 PM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection and Readiness see under

SUBJECT: Vaccination of Recruits Against Hepatitis B

- In the 2002 DoD Appropriations Conference Report, the Congress requested DoD to begin vaccinating all new recruits against hepatitis B, calling on DoD to "carve out" $8.4 million from the 2002 appropriations to begin the vaccination program.

- CDC Advisory Committee on Immunizations Practices currently recommends that all health care workers and infants should be vaccinated against hepatitis B, and a catch-up program to immunize older children be instituted as feasible. Vaccination is also recommended for infants of hepatitis B carriers, STD patients, adolescents with high-risk factors, and international travelers to high-risk countries. In addition, many states have required vaccination against hepatitis B as a requirement for school and/or childcare entry. DoD policy follows CDC recommendations. In addition, the Army soldiers assigned to South Korea, and military deployments to high-risk areas of the world are immunized. Initial review of data indicate that up to 20%+ of incoming recruits may already be vaccinated. As a result, the Services should consider serologic testing as part of the immunization program if it is cost beneficial.

- Although, initial review of data indicate low incidence of cases, and prevalence rates similar to the civilian population, vaccination of recruits (two-thirds of whom are teenagers) is a sound public health practice and will contribute significantly to reducing the burden of disease in the US.

- Annual estimated costs for serologic testing and vaccination of new recruits DoD-wide are $20 million. Services will need to carve out the program costs from both the FY02 and FY03 appropriations, and submit program costs as part of the FY04-09 POM.

RECOMMENDATION: Approve the memorandum and attachments, and sign the attached memorandum. (TAB A)

COORDINATION: TAB B

Attachments
As stated:

Prepared by COL [redacted] Program Director, PM&S, FHP&R, [redacted]
PCDOC: 34416

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

March 21, 2002, 3:00 PM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection and Readiness See under

SUBJECT: Vaccination of Recruits Against Hepatitis B

- In the 2002 DoD Appropriations Conference Report, the Congress requested DoD to begin vaccinating all new recruits against hepatitis B, calling on DoD to "carve out" $8.4 million from the 2002 appropriations to begin the vaccination program.

- CDC Advisory Committee on Immunizations Practices currently recommends that all health care workers and infants should be vaccinated against hepatitis B, and a catch-up program to immunize older children be instituted as feasible. Vaccination is also recommended for infants of hepatitis B carriers, STD patients, adolescents with high-risk factors, and international travelers to high-risk countries. In addition, many states have required vaccination against hepatitis B as a requirement for school and/or childcare entry. DoD policy follows CDC recommendations. In addition, the Army soldiers assigned to South Korea, and military deployments to high-risk areas of the world are immunized. Initial review of data indicate that up to 20%+ of incoming recruits may already be vaccinated. As a result, the Services should consider serologic testing as part of the immunization program if it is cost beneficial.

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- Annual estimated costs for serologic testing and vaccination of new recruits DoD-wide are $20 million. Services will need to carve out the program costs from both the FY02 and FY03 appropriations, and submit program costs as part of the FY04-09 POM.

RECOMMENDATION: Approve the memorandum and attachments, and sign the attached memorandum. (TAB A)

COORDINATION: TAB B

Attachments
As stated:

Prepared by COL [redacted] Program Director, PM&S, FHP&R [redacted]
PCDOC: 34416

TRICARE

TRICARE Management Activity

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

ACTION OFFICE FHP + R DATE 4-30-02 PCDOCS # 36054
(A) 34416

The attached correspondence is returned for the following reason(s):

- [x] Distribution
- [ ] Coordination
- [ ] Revision
- [ ] Correct Signature Block
- [ ] Correct Envelope Size
- [ ] Correct Letterhead
- [ ] Provide Original/Supporting Documents
- [ ] Provide SD 391
- [x] Retain for your Files

Additional Comments:

Signed Response Scanned into Docs # 36054

Health Affairs

Routing and Transmittal Sheet

Date Received: 3/29/02

_____ Dr. Winkenwerder		
_____ Mr. Wyatt	_____ DASD(FHP&R)	_____ OLA
_____ Ms. Tabler	_____ DASD(C&PP)	JC OGC TAB B
_____ CAPT Malone	_____ DASD(HPI&EA)	_____ OUSD (C)
_____ LTC Strawder	_____ DASD(HB&FP)	_____ Other (Specify)
_____ Capt Fahmy		
_____ Mr. Hurley		
4/1/02 A&CD	VK Reviewer	DMD

PCDOCS Information

SUBJECT: Vaccination of Recruits Against Hepatitis B

POC: COL (b)(6)

PCDOCS# 34416 **OSD/P&R#** NA

ACTION REQUESTED: ASD Sig

NOTES:

Please call (b)(6) **for pickup –** (b)(6)

HA/TMA Document Profile

21

48930

Subject:	Outline for Working with ASD- HD-Signed		
Author:	Dr. Winkenwerder	**Congressional Name:**	
Date of Document:	4/23/2003	**Input By:**	(b)(6)
OSD # :		**Profiler's Directorate**	Admin, HA
PR # :		**Response Signed By:**	ASD(HA)
Organization:		**Dt Response Signed:**	8/27/2003
Department:		**Dt Documents Mailed:**	8/28/2003
Assigned To	DHS	**Doc Type:**	103-03.1
Action Officer:		**Application:**	DOCSIMAGE
Prepared For:	DASD	**Previous Documents:**	
Suspense Date:	5/9/2003	**Related Documents:**	54351
Coord Office(s)			

Notes: 8/29/03 CLOSED, made copy of scanned signed response for DMD chron file. (b)(6)
CLOSED
On 8/28/03 DMD/PNT rec'd signed pkg, scanned, copied, filed, mailed orig, and fwd pkg w/ comeback copy to DMD/Sky5. (b)(6)
On 8/27/03 DMD/PNT pkg'ed and fwd to ASD(HA) for signature.(gjs)
(b)(6) 08/27/2003 4:19 PM):
8-27-03 Fwd to HA PCDOCS Admin. (PLT)

Beneficiary Info

Beneficiary Name:	
Address 1:	
Apartment #	
Phone #	
Email Address:	
City:	
State:	**Zip**

History

Created: 4/25/2003 HA PCDOCS Adr
Edited: 8/28/2003 HA Red Tag
Status: Available

Retention Schedule

Type: Keep

☐ From External Source?

Access Control

☒ Secure Document
☐ Enable Content Searching

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

AUG 27 2003

Paul

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HOMELAND DEFENSE)

SUBJECT: Mutual Support for Domestic Medical Preparedness and Response

My Deputy Assistant Secretary of Defense (Force Health Protection and Readiness) met several times with Mr. [redacted] and Mr. [redacted] of your office to discuss mutual concerns regarding emerging homeland security policies and programs, and the need for close coordination between our offices on medical matters.

They agreed that a formal mechanism must be established to ensure that issues arising from interagency and White House meetings (e.g. emerging homeland security matters in the health and medical realm) are routinely exchanged between us and our senior level staffs. To ensure you and I have the opportunity to share executive communication, I propose that we establish a quarterly meeting just for this purpose, beginning in October. Our conclusions may be used as guiding input for collaborative planning by both of our offices.

Ms. Embrey has proposed to support our mutual concerns by placing two subject matter experts from her staff to alternately work several days per week in your office to shape to our mutual satisfaction, important emerging policies with respect to medical readiness and consequence management support. I concur with this approach and would welcome the opportunity to have our staffs work together to shape this important capability to meet both of our needs.

I look forward to working more closely with you and your staff. If you have any questions or concerns about my proposal, please call my office or contact Ms. Embrey at [redacted]

Bill

William Winkenwerder, Jr., MD

[redacted] CIV, OASD(HA)/TMA

From: (b)(6) CIV, OASD(HA)/TMA
Sent: Wednesday, April 23, 2003 10 55 AM
To: [redacted]
Subject: FW Meeting with ASD McHale, Homeland Defense

-----Original Message-----
From: (b)(6) COL, OASD(HA)
Sent: Tuesday, April 22, 2003 3.54 PM
To: (b)(6)
Subject: Meeting with ASD McHale, Homeland Defense

Caroline Topics are

Biodefense vaccines
- Biodefense Vaccines & Immunologics IWG
- Bioshield
- Biodefense Vaccination Policies

Surveillance – CDC/DOD Capabilities
- SARS

National Laboratory Response Network
National Disaster Medical System
Response to Critical Incidents
- Anthrax
- Bot/Plauge

National Pharmaceutical Stockpile

I've attached some prep materials

(b)(6)

-----Original Message-----
From: (b)(6)
Sent: Tuesday, April 22, 2003 10:36 AM
To: (b)(6) COL, OASD(HA)
Cc: (b)(6)
Subject: Meeting with ASD McHale, Homeland Defense

Col (b)(6)

This meeting is scheduled for this Thursday at 8AM McHale's office is looking for a list of discussion topics and Dr Winkenwerder has requested Ms Embrey's office come up with the list for him

Will you send me the short list so I can let McHale's office know what the topics will be?

Thanks,
(b)(6)

23 April

Ellen –

Thank you for your comments at today's meeting with McHale. You should map out your/our set of objectives to be accomplished with ASD-HA's office, with timelines. Let's help drive his agenda I would like to see your outline by by May 9th –

Thanks,

Bill

Z003126-000031

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

22

HEALTH AFFAIRS

ACTION MEMO

May 6, 2003 10:00 AM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen Embrey, DASD, (Force Health Protection and Readiness)

SUBJECT: Report to Congress on Separations as a Result of Refusing to Participate in the Anthrax Vaccine Immunization Program (AVIP).

- At TAB A is a draft Report to Congress on Separations as a Result of Refusing to Participate in the AVIP with a cover letter from Dr. Winkenwerder requesting coordination.
- Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Secretary of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the AVIP.
- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: Sign letter at TAB A and forward for coordination.

COORDINATION: TAB B

Attachments:
As stated

Prepared by CDR (b)(6) DHSD, (b)(6) PCDOCs# 49498

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR UNDER SECRETARY OF DEFENSE, PERSONNEL & READINESS
ASSISTANT SECRETARY OF DEFENSE, LEGISLATIVE AFFAIRS
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
DIRECTOR, JOINT STAFF
DIRECTOR, MILITARY VACCINES OFFICE

SUBJECT: Report to Congress on Separations as a Result of Refusing to Participate in the Anthrax Vaccine Immunization Program (AVIP).

Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Secretary of Defense to submit to Congress an annual written report on the number of separations resulting from refusing to participate in the Anthrax Vaccine Immunization Program.

Request your coordination on the attached package no later than two weeks from the date of this memorandum.

My point of contact for this matter is CDR [redacted] who may be reached at [redacted] Coordinations may be faxed to [redacted]

William Winkenwerder Jr., MD

Attachments:
As stated

DEPARTMENT OF DEFENSE
REPORT ON
SEPARATIONS THAT RESULT FROM A REFUSAL TO PARTICIPATE IN THE ANTHRAX VACCINE IMMUNIZATION PROGRAM
(January 1, 2002, through December 31, 2002)

Service	Separations	Component	Rank	Total
Army	0	Active	N/A	0
	0	Guard	N/A	0
	0	Reserve	N/A	0

Note: One reported separation occurred in the 2003 and will be reported in a subsequent report covering the 2003 timeframe.

Navy	0	Active	N/A	0
	0	Guard	N/A	0
	0	Reserve	N/A	0
Air Force	1	Active	E-4	1
	0	Guard	N/A	0
	0	Reserve	N/A	0
Marines	0	Active	N/A	0
	0	Guard	N/A	0
	0	Reserve	N/A	0

Services Total ----------→ 1

SUBJECT: Report to Congress on Separations as a Result of Refusing to Participate in the Anthrax Vaccine Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
Under Secretary of Defense (P&R)	_____	_____	_____
Assistant Secretary of Defense (LA)	_____	_____	_____
DoD, (OGC)	_____	_____	_____
Director, Joint Staff	_____	_____	_____
Director, Military Vaccines Office	_____	_____	_____

(23)

PROTECTING THE HEALTH OF DEPLOYED FORCES: LESSONS LEARNED FROM THE PERSIAN GULF WAR

Tuesday, March 25, 2003

House of Representatives,

Subcommittee on National Security,

Emerging Threats, and

International Relations,

Committee on Government Reform,

Washington, D.C.

Committee Hearings

of the

U.S. HOUSE OF REPRESENTATIVES

Michael E. Sukgatt
for Dr. Wm. WINKENWERDER.
13 May 2003

OFFICE OF THE CLERK
Office of Official Reporters

I'm a tennis fan. I think we'll start with you, Dr. Winkenwerder.

STATEMENTS OF WILLIAM WINKENWERDER, JR., M.D., M.B.A., ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, DEPARTMENT OF DEFENSE, ACCOMPANIED BY MICHAEL E. KILPATRICK, DEPUTY DIRECTOR FOR THE DEPLOYMENT HEALTH SUPPORT DIRECTORATE, DEPARTMENT OF DEFENSE; ROBERT H. ROSWELL, M.D., UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY K. CRAIG HYAMS, CHIEF CONSULTANT, OCCUPATIONAL AND ENVIRONMENTAL HEALTH, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF WILLIAM WINKENWERDER, JR.

Dr. WINKENWERDER. Thank you, Mr. Chairman. Mr. Chairman, members of the subcommittee, thank you for the opportunity to appear here today. With your permission, I will summarize my written statement. And also with me today to answer questions, if that is acceptable to you--.

Mr. SHAYS. That is fine.

Dr. WINKENWERDER. --is Dr. Michael Kilpatrick, whom you've already introduced.

I want to begin--.

Mr. SHAYS. Let me just ask, can you all hear in the back of the room? No. I need you to speak up a little louder. Thank you very much. It is the silver mike that projects your voice.

Dr. WINKENWERDER. All right. Thank you.

I want to begin by adding my condolences to those of President Bush and the Secretary of Defense for the families' of the United States casualties since operations began last week. Each of you is in our prayers. Our country's ultimate weapon against any enemy is the valor of the men and women in our armed services who serve the cause of freedom. They comprise the most powerful force on Earth, and, in this particular case today, a force for peace and liberation of the Iraqi people.

On behalf of all the men and women in medical service to our Armed Forces, I want to recognize the cause for which many have now given their lives and the efforts to ensure the safety of everyone engaged in this conflict. The courage, skill and discipline of our military medical personnel is matched only by the high-quality, swift and effective medical care that they provide.

You have already seen reports by embedded media of heroic acts by U.S. Armed Forces medics to save lives; for example, the MediVac crews and surgical teams that have gone into very dangerous situations. We can be assured that today such acts

will continue, and they will continue until our final mission is accomplished. In Operation Iraqi Freedom we have more than sufficient capability to move casualties from their point of wound to any level of care their injuries might require. We have more than sufficient medical supplies, including blood supplies, for all of our troops operating in the field, and all of this is regulated by an integrated logistics system in the theatre.

Our medical and soldiers--our medical medics and soldiers are trained, equipped and prepared to operate in the contaminated environment, if necessary, with equipment decontamination and antidotes. We are prepared for what Saddam Hussein might attempt to deliver to United States forces.

As the Assistant Secretary of Defense for Health Affairs, safeguarding the health and safety of our military members is my highest priority. Our force health protection program has made great strides based on the lessons learned from the Gulf War and subsequent deployments. I believe our efforts are in line with your own objectives, as these have been expressed in public law.

The Department is committed to providing an ongoing continuum of medical service to service members from entrance into the military through their separation and as many transition to the Department of Veterans Affairs after their

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service.

The vigorous requirements of entrants' physical exams, periodic physical examinations, periodic HIV screening, annual dental examinations, routine physical training and periodic testing and then regular medical record reviews are all part of this continuum.

We've established a comprehensive program to sustain and document our service members' health and fitness for duty. All deploying personnel are required to complete individual predeployment health assessments. These health assessments are coupled with a review of medical and immunization records. We look at whether there is a DNA sample on record, and if a blood serum sample has been drawn within the prior 12 months. This information is considered, along with the availability of personal protective and medical equipment. Predeployment briefings on deployment-specific health threats and countermeasures are also provided. All personnel complete postdeployment health assessments when they return.

Any indication of health concerns results in an individual health review and, if appropriate, referral for further medical evaluation or testing. These health assessments are to be maintained in the individual's medical records and centrally in electronic format in the defense medical surveillance system.

Additionally, all immunizations are tracked by

service-specific systems, and the data are fed into a central database. We're currently transitioning from paper-based medical records to automated medical records for patient encounters and reporting of nonbattle and disease events.

Health care focused on postdeployment health concerns is available through both military and VA providers who are using jointly the postdeployment health clinical practice guidelines. These guidelines were designed to ensure that the medical providers render effective and appropriate responses to the medical concerns of our deployed service members and their families upon return.

We've established three deployment health centers. One focuses on deployment-related health care, one on related health surveillance, and the third on health research. All are working towards prevention, treatment and understanding of deployment-related health issues.

Desert Shield, Desert Storm taught us knowledge of the environment is vital if we're to protect the health of our service members. Today the Army's Center for Health Promotion and Preventive Medicine conducts environmental health assessments that enable intelligence preparation of the battlefield before and during deployments. This unit employs equipment to monitor the combat environment, and it samples soil, air and water. They also perform extensive environmental assessments of staging areas and base sites.

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This information is used to make determinations of where we can safely put our military people. We also archive that information so that we can go back amend, look at it later to evaluate for correlation between an area of known or suspected exposure and illness that may appear in the future.

In the past few months, we've been working to develop and have implemented a joint medical workstation. This is an important development. We're using a Web-based force health protection portal to our classified system, and DOD now has the electronic capability to capture and disseminate real-time and near real-time information to commanders about in-theatre medical data, patient status, environmental hazards, detected exposures and critical logistics information like blood, beds and equipment availability.

The transition from paper-based processes to automated systems offers us a much greater opportunity for collecting and analyzing medical information that is useful in real time. We proceed with that work with an awareness of operational security and personal security for our service members who expect their medical records to remain confidential.

When we deploy, we bring a formidable medical capability. This includes far-forward surgical care, and we've seen this on the battlefield just in the past few days; medical evacuation assets, with the ability to provide intensive

care, ICU care, inside an airplane; and ship-based medical capabilities.

In the event of a biological or chemical attack, we also maintain significant decontamination equipment and the ability to treat both chemical and biological casualties. All services have made training improvements, and they've been significant to do that, to assure that their medical personnel can work successfully in a contaminated environment and decontaminate and rapidly evacuate their patients to safer environments.

Much has been accomplished in the past decade. Our level of effort and our capability to protect our forces is unprecedented in military history. However, today we face new and deadly threats and the possibility that a brutal regime would use chemical or biological weapons.

As military professionals and as health professionals, we're well aware that war, and particularly this war, involves real risks, but our message to you, to our service members, to their families, to the American people is that we're prepared, and we have extraordinary capability to protect and care for our people.

Mr. Chairman, I thank you again for inviting me here today. I'm pleased to answer your questions, and I know there will be many. Thank you.

Mr. SHAYS. I thank you.

I'm pretty clear, when we voted on this law, what that meant to me. I'm just curious to know why we're not seeing it implemented. And, Dr. Winkenwerder, would you kind of tell me why not?

Dr. WINKENWERDER. We believe that we are following the law, and that we're doing it in a way that makes sense. As you read--and I think it is very helpful to read the actual language of the law here--you note the fact that we're required to develop a system to assess the medical condition. I think that's the operative point. It is to understand what is the baseline health, and when one is looking at a young generally healthy population, the most useful information to ask--or to determine the health of the--the health status of that individual is a set of questions. I think, from my experience as a physician, that history-taking is really the most useful information to get a picture of the health status of the individual, not so much a hands-on physical examination. Usually those types of examinations are of very limited value.

We do perform periodic full physical examinations, along with the drawing of blood, but it is our view that we are meeting the letter and the spirit of the law--.

Mr. SHAYS. Let me just tell you, from my standpoint, you're not meeting the letter of the law clearly, and I don't even think you're meeting the spirit of the law.

So I'd like to know where it says that this examination should be a self-assessment. Where in the law do you read self-assessment?

Dr. WINKENWERDER. Well, it is not only a self-assessment. There is a review by a medical provider with questioning by the medical provider that gets at the history of the individual, the medical history of that individual.

Mr. SHAYS. The challenge that I have is that we've had countless numbers of hearings since Gulf War, because our folks came home sick; 125,000 thousand are registered with the VA out of 700,000. And it started out when we had our hearings that the government officials would respond and say, no one came home sick, and our second panel were people who were sick, and you knew they were sick just looking at them. And then when you heard their history--so we then reversed it. So we had them go first and then had the VA and DOD come second and be the second panel.

What I'm struggling with right now is we didn't accept self-assessment when our VA folks--when our military folks came back. We gave them a physical. And we didn't ask them to fill out a questionnaire. With we gave them a physical. I can understand you'd have them fill out a questionnaire, but doesn't the law say that there's supposed to be a medical examination?

Dr. WINKENWERDER. Well, again, medical examination and physical examination are not synonymous. Some may have read that to be the same, but as a physician, I would say that they're not the same.

Mr. SHAYS. You know--.

Dr. WINKENWERDER. What we're attempting to do ~~to~~ really--to answer your question, which I think is a very fair question, is to ensure that we have a good baseline of information for every individual that gives us what we need to know about the health status of that individual.

Now, I will--I'll stop at that. I was going to go into the issue of the postdeployment.

Mr. SHAYS. Well, I'm sure you'll have an opportunity.

Let me just say before I recognize Mr. Kucinich that one of the challenges with the concept of medical examination versus physical examination is that it reminds me of what was alluded to by Mr. Kucinich when we went to DOD and questioned whether our troops had been exposed to chemical weapons, and we found them using the word, they weren't exposed to offensive use of chemicals.

And then we had a hearing in which we had a video of the blowing up of Khamisiyah, and DOD has a press conference on Friday at 4 o'clock before our Tuesday hearing to disclose that our troops were exposed to defensive chemical exposure. And I just hope we're not getting a play on words here.

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So at any rate, Mr. Kucinich, you have the floor.

Mr. KUCINICH. Thank you very much, Mr. Chairman. Again, I want to thank you for demonstrating your concern for the men and women who serve by calling this hearing.

Dr. Winkenwerder, I would like to ask you about the press release that you issued in January. In it you made a broad statement. You said the U.S. military is prepared to protect its personnel against the use of biological weapons. That's a direct quote. You stated that, quote, America's troops are well trained and protected with a robust multilayered set of defenses against bioweapons, unquote.

Now, you say the troops are prepared. Does your definition of prepared include training in a realistic environment?

Dr. WINKENWERDER. Yes.

Mr. KUCINICH. But, Dr. Winkenwerder, the GAO testified before this subcommittee last fall, quote, no realistic field exercises for medical personnel of chemical and biological defense have been conducted. None. How can you say that you're prepared with no chem-bio field exercises for your medical personnel?

Dr. WINKENWERDER. That study, if it is the same one that I believe you're referring to, was in 2001. That is the time when that information was collected was approximately 2 years ago. And I can just tell you that since that time there has

been an intensive effort to train a large number of people, both nonmedical and medical.

When I took my position about 18 months ago and then was before this committee about 14 months ago or 13 months ago, I think, now, I committed to you that this matter of training people would be one of my highest priorities.

Mr. KUCINICH. Thank you.

Dr. WINKENWERDER. And let me just say, we issued--.

Mr. KUCINICH. Doctor, I've got a question here that is a follow-up, and I appreciate you taking this time to answer the question, but I have another question.

Dr. WINKENWERDER. Okay.

Mr. KUCINICH. And that is that are you familiar with the war game called Millennium Challenge 2002?

Dr. WINKENWERDER. Generally. So yes, I--.

Mr. KUCINICH. You say we're talking about 2001. Now let's go to 2002. That was the largest war game in American history, and it was also the most expensive at $250 million. It involved over 13,000 soldiers, sailors, airmen. But when the commander claimed the enemy wanted to simulate the use of chemical weapons, he was told to disclose his troop locations and be destroyed. He told the Army Times that instead of testing against the most urgent threats, the game was rigged. Now, how can you say, 2002, that you're prepared, when from this report realistic field testing had not been done?

Dr. WINKENWERDER. I'm not going to try to speak for our commanders in the field, Army officers that planned and conducted those exercises.

Mr. KUCINICH. But how do you answer the question, though? Do you have an answer to that question?

Dr. WINKENWERDER. Well, I can't answer your question, because I'm not in a position--.

Mr. KUCINICH. Let me move on to the next question if you can't give me an answer.

Mr. WINKENWERDER. Well, let me just stay this. I stand by what I've said in terms of the preparation of our medical personnel to operate in those environments, the preparation and training to care for people, whether there's been exercises--.

Mr. KUCINICH. Doctor, Doctor, with all due respect, you said you stand by what you said, but I gave you an example that contradicted what you said, but you still stood by what you said. Now, I just want that on the record.

Does your definition of "prepared" include providing troops with the minimum level of necessary chem-bio equipment as said by you and the Defense Department?

Dr. WINKENWERDER. The minimum level of equipment to protect people would be part of being prepared, absolutely.

Mr. KUCINICH. And in light of all the equipment shortages identified by the GAO, the critical deficiencies

JSLIST suits, which then you could interpret as not meeting the minimum requirement. The JSLIST suits have 30 days each to them.

Dr. WINKENWERDER. Right.

Mr. KUCINICH. Mr. Chairman, here is the letter.

Mr. SHAYS. We'll put that in the record.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. KUCINICH. Here's the letter, here's the response, and it's very clear the answer was no.

Mr. SHAYS. For the record, since this is so technical, find the--where the no is on that letter.

Mr. KUCINICH. The text of this does not answer the question as far as certification.

Mr. SHAYS. Okay.

Mr. KUCINICH. She asked for certification. If the Secretary of Defense will not certify that these suits are okay, the American people have a right to know that. The answer was no.

Mr. SHAYS. I got the same letter, and my interpretation of it was that he was certifying that they would have--well, I first have to make sure I have the same letter. I'll look at it and then--.

Dr. WINKENWERDER. I want to attempt to answer your question, even though I want to be clear that the issues you're talking about are not within my area of responsibility, but I don't want to avoid trying to answer the issue that is in front of us.

Mr. SHAYS. I realize we have a 5-minute rule, but I will extend a little more time if a Member, you know, is nervous that the answer is a little long. But I don't want to have the answer not be thorough enough to respond.

Dr. WINKENWERDER. The issue with respect to chemical

protective suits, I believe you're referring to, is the number of them, and each service member has been issued at least two, and I'm told--the information I have is that each will have three within a matter of less than a week.

Now, obviously that's to reach 100 percent. So they've been moving towards that target obviously for the last several weeks. So the--and then I think there was another issue with some defective suits, and, again, I'm going to relate to you my best understanding of that, but my understanding is that those have been removed from the inventory, and there was a very deliberate, scrupulous effort to remove all of those suits, and they are not being used in this situation today.

Mr. SHAYS. Well, we'll be here for a bit, so we can nail this one down.

Mr. Turner.

Mr. TURNER. Dr. Winkenwerder, I just recently met with representatives from the Ohio National Guard, and they were talking to me about the issue of National Guard reservists that do not have a continuous health care coverage. They have indicated numbers between 20 and 40 percent of the reservists do not have continuous health care coverage for insurance.

To what extent do you have a concern that that might have an impact on the medical condition of those deployed?

Dr. WINKENWERDER. If I might just ask you, the 20 to 40 percent, is this without health insurance coverage, and they're sort of private--.

Mr. TURNER. Correct. Correct.

Dr. WINKENWERDER. My hope is that it would not impact upon their health status. We do have a check on that, however, and that is that we require a certain level of medical readiness before people come on to Active Duty, and so we would hope to screen for and identify individuals who are not medically ready to serve.

Obviously the issue of health insurance or the lack thereof among certain members of the population is an ongoing problem.

I will say that with respect to caring for National Guard and reservists and their families, when they come on Active Duty, they are eligible for the military health system benefit program, TRICARE. We've made--in a change that we had just 2 weeks ago, made it easier for them to gain coverage for their families. There had been a glitch in the system where if a person was living, for example, in one part of the country and got deployed from another, that because they weren't residing with their family--or their family wasn't residing with them, they would not be eligible. We changed that. They're now eligible right then and there. There was also a hurdle that one had to be activated for 180

days. We changed that and said they only need to be active for 30 days. So all those benefits are commensurate between reservists and Guard and our ongoing Active Duty.

And we gladly did that. Our reservists and Guard are playing a very important role in this conflict, and particularly so in the medical area. So it's important that we take care of them.

Mr. TURNER. Thank you.

Mr. SHAYS. Thank you. I think we will go to Mrs. Maloney.

Mrs. MALONEY. A few, Mr. Chairman, and I want to be associated with your comments and those of the panel in appreciation of our men and women who are serving in the armed services.

I would like to ask some questions that were raised in this book, Saddam's Bomb Maker. It was written by Khidir Hamza, who says that he was in charge of Saddam's efforts to secure materials from foreign governments to build nuclear bombs, and he also talks about their chemical and biological weapon program. And I would like permission to place in the record page 244 and page 263.

[The information follows:]

******** COMMITTEE INSERT ********

Mrs. MALONEY. And he raises really an alarming statement, and I would like to just quote from his statement here. He says, the Gulf War syndrome was well known to everyone in Iraq, but Saddam remained silent. In this he had a secret ally, the U.S. Pentagon, which continued to deny that there was proof of a war-based disaster--war-based disease despite growing evidence to the contrary. But evidence soon leaked of allied forces blowing up chemical dumps during the war and of the U.S. Government efforts to suppress repeated efforts of reports of the contamination of our troops.

He also on page 244 talks about Saddam's effort to put biological--or that he did put, according to him, biological and chemical weapons into missiles that he was going to fire on the U.S. military if they went into Baghdad, but that he had a more sinister plan in that he buried chemical and biological weapons in southern Iraq, knowing that the tactics of the U.S. military would be to blow up the bunkers; therefore, they would release the contaminated material, they would not even know that they were affected, and that they would then be laden with chemical and biological disease from these terrible weapons.

I'd like to ask you if you, number one, have read the book; number two, your comments on what Saddam's bomb maker, Mr. Hamza, who is now a--has defected to the West and I

understand is working with our military and has been very outspoken against Saddam in hearings and publicly and so forth.

Dr. WINKENWERDER. I have not read the book, Congressman. I have heard of the book. And by all accounts, it is a--from what I understand, is a reliable piece of information.

Mrs. MALONEY. Are you aware that our troops were exposed to these biological weapons? The allegation that he makes that out Pentagon knows, that Saddam knows, that people in Iraq know that our troops were exposed to these terrible chemicals in the Gulf War?

Mr. WINKENWERDER. Well, from all the information that I've been presented during my tenure, no one has ever indicated to me that there is any knowledge of an acute exposure or the exhibiting of symptoms that would suggest an acute exposure to chemical or nerve agents during that conflict.

Mr. SHAYS. Would the gentlelady yield? I'll make sure she gets additional time.

Mrs. MALONEY. Sure.

Dr. WINKENWERDER. That is a separate question, an acute exposure, someone who is acutely ill, than the issue of whether there were low levels of exposure--.

Mrs. MALONEY. Were there low levels of exposure?

Mr. WINKENWERDER. Well, that is what the whole Khamisiyah incident is about.

Mr. SHAYS. This is very important, and I don't want--since this is testimony under oath, I do want to make sure. There are really two issues, but one issue is sites. The only one that the Department of Defense has acknowledged is Khamisiyah. So I would love it if you would ask the question of whether there were other sites, and then get into this other shoe. But I want to make--.

Mrs. MALONEY. Were there other sites besides Khamisiyah where they were exposed to chemical weapons?

Dr. WINKENWERDER. Not to my knowledge.

Dr. Kilpatrick.

Dr. KILPATRICK. I can answer that. In looking at--.

Mr. SHAYS. A little closer to the mike, Doctor.

Dr. KILPATRICK. In looking at the air war campaign, it's very clear that his storage sites at Al Muthanna and Mahamadia, that there were releases of chemical agents. In one location we have no indication there were American troops in the area where that plume would have gone, and the other area there were possibly up to 70 Special Forces people in that area, but there were no coalition forces or American forces in that area.

Then Khamisiyah is the third area, and that's been widely publicized and put out, and certainly we've identified the

101,000 American forces who were in that hazard area that was determined.

Mrs. MALONEY. Well, Mr. Hamza alleges that Iraqis were likewise exposed, and women gave birth to deformed children. People died of cancer early. People had Parkinson's-like neurological problems. And he blamed it all on malnutrition, according to this professor, and he likewise said that the same symptoms--or he alleges are now in the troops who regrettably were exposed to these terrible chemicals in the war.

If you have any other information, if you could get back to the chairman on it, on how many troops we think were exposed, where they were exposed and what chemicals--what chemicals do we think they were exposed to? Do you have an idea of what the chemicals were or biological weapon they were exposed to? Do you have an idea what it was?

Dr. WINKENWERDER. Yes.

And Dr. Kilpatrick.

Dr. KILPATRICK. In all three areas, it was sarin--cyclosarin were the agents that we were concerned about. As far as biological agents, we don't have any indication that American troops were exposed to biological agents. We do know that bombs and rockets filled with biological agents were found by the United Nations Special Commission, but we have no indication that they were ever

launched against Americans.

Mrs. MALONEY. Excuse me. Go ahead, Mr. Chairman. My time is up. I'd like to continue with this questioning.

Mr. SHAYS. Why don't you ask the next question, and then we'll--.

Mrs. MALONEY. If you have another question.

Mr. SHAYS. I just want to say to you that it's a little unsettling to me, because we've had so many instances--DOD has insisted that the only place that our troops were exposed was at Khamisiyah, and now we're hearing that we had other troops that were nearby. So I'm not sure whether I should consider this new information or old information, but it is a little unsettling to me, because either way it's new to me. And so I want to be clear that you have said that--there were two other sites. I want you to say what those sites were, and I want you to be very clear as to what level of the amount of chemicals we think were on site and compare them to Khamisiyah.

Dr. KILPATRICK. Those reports we released in the last 2 years, and I can get you specific details. Al Muthanna is one site, and Mahamadia is the other site. These were large production storage sites in Iraq near Baghdad, and they were damaged during the air war. We don't know exactly which day, because the bombing ones in each of those sites were somewhat over 17 days. We don't know whether the release was at one

time or over multiple periods of time. The determination of the hazard area assumed a release of all agent at one time, and the amount of agent is information that we receive from CIA, and they have recently released a report to give that amount. We can provide that to you.

Mr. SHAYS. Well, I understand we have the GAO looking at this, but--the plume modeling--but one thing I want to ask you would be then how many American troops do you think--first off, it's unsettling no matter what humanity was there, but how many Americans do you think were at--.

Dr. KILPATRICK. At Al Muthanna, we don't believe there were any Americans in the area. At Mahamadia, we believe that there were up to 70 Special Forces, and we have identified them and notified them.

Mr. SHAYS. And have you notified the VA?

Dr. KILPATRICK. And that's been done also, yes.

Mr. SHAYS. Okay. I thank the gentlelady for asking those questions.

Mrs. MALONEY. Mr. Chairman, could I follow up with other sites that--.

Mr. SHAYS. Yeah. Why don't we do that real quick.

Mrs. MALONEY. They mentioned that they had it really as a war strategy, burying these chemicals knowing we might bomb them. The symptoms would not arise until weeks, months later. They would not know where it came from.

MEK

RPTS JURA
DCMN MAYER
[1:59 p.m.]

Mrs. MALONEY. But they mention that--he mentions that they were buried, thousands of chemical weapons in southern Iraq at Basra, Nasiriyah, Simawa, Diwaniyah, and Hilla, the likely routes of the allied invasion. And he says that that's what they did, and that we walked into that trap.

Dr. WINKENWERDER. I think you can conclude that this provides a good window into the twisted mind of Saddam Hussein.

Mr. SHAYS. But is that an answer that is a yes?

Dr. WINKENWERDER. We will take that information for the record, and certainly--.

Dr. KILPATRICK. And I have no information at this time to be able to comment positively or negatively. I have no knowledge that that in fact is true.

Mrs. MALONEY. Just very briefly, for years, literally, the Pentagon denied that they were exposed to chemical weapons, and he says that in the book. Why did we do that when we knew that they were exposed? And when did we acknowledge in the time frame that they were exposed to chemical weapons?

Dr. WINKENWERDER. Let me just say this. I cannot speak for those who had my responsibility or were associated with

those responsibilities 5, 6, 7 years ago, at the time the information began to come to light

Mrs. MALONEY. But can you get us that information?

Dr. WINKENWERDER. Well, what I can tell you is that I am committed to getting that kind of information out and making it available, and that we know what happened. I think it is in everyone's interest, our service members, their families.

Mrs. MALONEY. And you will get that information to the chairman, so we can--.

Dr. WINKENWERDER. We will take your request. But I just want you to know that I am committed to making that kind of information--and we have sought to establish a track record with this for the release of the information regarding the SHAD.

Mr. SHAYS. Let me just say. You are not just taking the request. You are going to get us the information, correct?

Dr. WINKENWERDER. We will.

Mr. SHAYS. Thank you.

[The information follows:]

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Mr. SHAYS. Mr. Murphy, thank you for being so patient.

Mr. MURPHY. Thank you, Mr. Chairman. Are there differences between British troops and American troops in the Gulf War syndrome incidents?

Dr. WINKENWERDER. I am going to turn to Dr. Kilpatrick for that.

Dr. KILPATRICK. I think the research that has been done to date shows that there is tremendous similarity, not really difference. As far as numbers of British troops, the numbers of course are smaller. They had deployed some 50,000 and they've had some 3,000 people go through their health assessment program, which is very similar to our clinical--comprehensive clinical evaluation program, the VA's Persian Gulf registry program.

Mr. MURPHY. Is anybody still pursuing the line--I found the article from Pain and Central Nervous System Week from a year ago, a year ago last week, saying that research teams identified clusters of postcombat syndrome, some debilitating syndrome from the Boer War and the First World War, somatic disorder focused on the heart from the First and Second World Wars, and neuropsychiatric syndromes, in essence saying that every war seems to have those.

Are people still following that or has that been seen as not scientifically valid to say that perhaps Gulf War syndrome is similar to what is seen after every war?

Dr. WINKENWERDER. My answer to that is that even though different kinds of issues and maybe even some similar kinds of issues do occur in all wars, we saw something and later better understood something coming out of the Gulf War that was a constellation of symptoms and complaints that were quite real, that were occurring in higher proportion among those people who were deployed than among those who didn't deploy.

So I would distinguish what we saw there from what maybe had occurred in other, prior wars.

Mr. MURPHY. I have also read some studies that have looked at animal studies of some chemicals used for example for insect control and other things, particularly DEET, permethrin, and an antinerve gas agent, pyridostigmine bromide--I hope I am pronouncing that right--PB, which was administered to both U.S. and British troops; and have found a number of problems--cell degeneration, cell death, animal behavior differences--and have found that those things were exacerbated more when the animals were under stress, et cetera.

Given that these were--there also seems to be an additive effect, a multiplier effect, that any individual chemical, when used alone, doesn't have that, even when the dosage of those chemicals is low. But when you add them together, you end up with some pretty severe outcomes.

With those, that kind of data, have there been changes in how the military is using such things as immunizations, insect control agents, and other things in dealing with the Gulf War now?

Dr. WINKENWERDER. First of all, let me just say that the area that you are talking about is an area of research that we continue to support and believe is very important to better understand whether a variety of simultaneous or near-simultaneous insults from low-level agents produces these effects. And that is very important work. It is ongoing. We are supporting that.

I would distinguish that from immunizations. From my perspective, particularly with respect to the use of the anthrax vaccine, we have had millions of doses given. We have followed all of that very closely for the last several years, and from my perspective, don't believe that there is any--and I think others would corroborate this, experts, outside experts, Institute of Medicine--that there is any association between the use of that vaccine and any of the symptoms that we saw.

Mr. MURPHY. Not even an interactive effect with these agents?

Dr. WINKENWERDER. Not with respect to the vaccine.

But I think your other point is very well taken in terms of low-level chemical exposure, nerve agents and pesticides.

The way they work in the body is similar, and so you could hypothesize or theorize that there might be this additive effect. And I think that is important work that is ongoing, and we are supporting that.

Mr. MURPHY. Is that changing, though, how--a lot of what is being done that we are talking about here is the epidemiology of exploring pre- and post-data. But I am just wondering if there has been a difference in handling things like insecticides and knowing that there may be nerve agent exposure.

Dr. WINKENWERDER. There have been some changes in the use of pesticides and pesticide management policy, and I think the long and short of that is that they are used more sparingly and more carefully, and with a lot better documentation and control. So that is something that we had already begun to respond to and change practice.

Mr. MURPHY. One other factor I want to ask, perhaps because of my background as a psychologist. But what I see frequently in these studies is the impact or the interactive effect of stress upon any of these.

Can you comment on how that works?

And it also relates to some of the comments--you talked about soldiers who are in the actual theater of war and those who remain home.

Dr. WINKENWERDER. I think it is certainly plausible that

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stress could add to any sort of physiologic--yeah, and as Dr. Roswell was saying. But I would distinguish that from saying that stress alone is responsible for the symptoms; I don't happen to believe that.

Mr. MURPHY. I understand. I just think as we discuss these things, as one is looking at pre- and post-histories, that getting some understandings of the mental health, which is oftentimes extremely difficult to get from just a self-disclosing questionnaire, is very important.

That is not to say that these folks have mental illness, that is not--although some may have post-traumatic stress syndrome. It is important to understand that stress has an impact on many diseases, cancer being one on which there has been extensive amounts of research. And one that you can't build a cure to protect you from that, but it is one that we need to be aware of, how we help soldiers with that.

Dr. WINKENWERDER. We agree with you.

Mr. MURPHY. Thank you, Mr. Chairman.

Mr. SHAYS. Thank you, Mr. Bell, your patience. And you have the floor.

Mr. BELL. Thank you very much, Mr. Chairman.

I want to follow up on some lines of questioning that were begun by my colleagues, Congresswoman Maloney and Congressman Kucinich. I want to begin with this letter that Congressman Kucinich referred to, since we didn't really--I

know it's been offered for the record, Mr. Chairman, but we didn't really get to delve into the text.

And I would disagree with my colleague that it was a no; actually, it was a little more disturbing than that in that it was a non-answer completely. And Representative Shakowsky had asked a very direct question in her letter to the Department, requesting information on the suits and would they provide protection for our troops. And I am not going to read the entire letter since it has been entered in the record, but where you come to the paragraph where he could easily answered the question yes or no, he says, instead:

"since Operation Desert Storm, the Department of Defense has fielded a new and improved CD, defense detection equipment and individual protective equipment. Every service member, to support near-term operations in Southwest Asia, will carry at least two of the newer, joint service lightweight integrated suit technology JS list suits and will have an additional two suits in contingency stocks. The contingency suits will be the battle dress overgarments, BDOs, until replaced by JS list suits." .

So we know what they will have in terms of supplies, but we have no idea whatsoever whether they are safe because nowhere in the letter of response does it say that they are safe. And I think the frustration felt by me and some of my colleagues in recent weeks is that it is hard to get a direct

answer.

And the purpose of this hearing is to focus on lessons learned from the Persian Gulf. Persian Gulf War syndrome was not something that was immediately announced after the Persian Gulf War, if I recall correctly. I was not--obviously not serving as a Member of Congress at the time, but if memory serves, it took months, perhaps years in some cases, for all the information regarding that syndrome to filter out regarding what people had been exposed to.

And we are highly critical of our enemies in this conflict as to their propaganda machine. And I am not saying that our information system compares to that in any way, shape, or form, but it does seem that we do engage in misinformation sometimes. And I would like for your comments on that and whether you think that we could learn a lesson from the Persian Gulf War and perhaps do a better job of educating both Members of Congress and the American people as to the risk we face. Because I don't think any right-thinking individual in this country believes that we don't face very serious risk by going forward with this conflict.

Dr. WINKENWERDER. Congressman, I can just assure you there is no thought of misinformation or trying to misinform either our service members or the public. That does not serve any of us in the short run or the long run.

I think that, from my review of what transpired in the past, it did take months and years to find out more about what happened. I do believe that that has informed a lot of action and activity on the part of the Congress, as well as DOD and VA, to put into place better recordkeeping, better tracking, better equipment, better monitoring detection across the whole board.

And my conclusion is that we are prepared. However, we face an enemy that is prepared to use some of the most lethal and awful weapons we have ever known, and that is a daunting situation. So I don't think there is any effort to tread lightly over this issue or to not acknowledge the seriousness of the risks that are out there. These are very serious risks that we face.

Mr. BELL. And I think that is a very important statement, because by putting a statement on the record that we are prepared, basically you put yourself in a position that, if we come up against something that we really didn't know we were going to come up against during the course of this conflict, then you are in a box if we come back and face something and you have to say, well, we weren't prepared completely for that.

But aren't we in a situation, Doctor, where it is almost impossible--based on your statement about what he is prepared to do, almost impossible to completely prepare for what we

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might face?

Dr. WINKENWERDER. That's a judgment. I think we have very good information about what the threats are. We have good information about the detection capabilities. We have good information about the protective capabilities of the equipment and suits. We have good information about the protective capability of medical countermeasures. So I think that we are prepared.

There are certain situations, there are circumstances that one can envision where an enemy can create harm and damage, and we have already seen that in the war thus far. So being prepared does not mean being able to completely prevent any adverse outcome in every single service member serving.

Mr. BELL. Can I ask one more question?

Mr. SHAYS. Sure.

Mr. BELL. As far as the lessons-learned category, are we prepared, after we face whatever we are going to face in this conflict, to come back and say, this is what we are looking at, this is what we are testing our troops for?

Dr. WINKENWERDER. Yes.

Mr. BELL. And to treat that instead of trying to pretend that we didn't face any of those things?

Dr. WINKENWERDER. Absolutely. We will be looking at people very carefully after deployment. And we have a

process in place. We are looking at and currently evaluating that system to ensure that it will collect all the information in a timely way that we want and think that we might need.

Mr. BELL. Thank you very much, Doctor.

Thank you, Mr. Chairman.

Mr. SHAYS. Thank you.

Just for the record, my counsel, our counsel, the committee's counsel reminds me that all three sites had been discussed. The only thing that we think is a bit new is that maybe we had Special Forces near one of those sites, but that the committee is trying to determine where those plumes went. So I just want the record to state that.

Also say--Dr. Winkenwerder, you are getting all the questions right now.

Dr. Roswell, you are going to get some.

But you have--you have, for the record, turned over some stones and have been very cooperative and very helpful with this committee. So these are big issues. But I do want the record to note that you are been pushing DOD to be more candid, to be more open, and to treat these very serious questions that you are being asked with a lot more attention than has been done in the past. I do want the record to note that at well.

Dr. WINKENWERDER. Thank you.

Mr. SHAYS. Mr. Janklow.

Mr. JANKLOW. Thank you very much, Mr. Chairman.

You know, let me, if I can, ask questions kind of like we used to take our English lessons--what, where, when, how, why, and to what extent--if I can.

Let's talk about the current war that we are in. In order to try and make sure that we don't have some of the problems that--and nobody wants to repeat the problems of Desert Storm. One, is it--will it be difficult at all--and you used the phrase before, production areas, storage areas. Would it be difficult now, if we come across any production areas in the country, to document, using GPS, GIS, whatever, exactly where these locations are;

Two, exactly what storage facilities we come across within the country;

Three, exactly where utilization of chemical, biological types of weapons are used--three; and

Four, to the best extent possible, identifying, if not the individuals, at least the units that are in the area so that all of these kinds of problems that we have wrestled with from Desert Storm don't have to be revisited?

Is there a plan in place to deal with it that way?

Dr. WINKENWERDER. I will try to give you the best answer I can. But I will note that, again, you are asking very good

questions. They are out of my--.

Mr. JANKLOW. Are they out of your bailiwick?

Dr. WINKENWERDER. They are really, truly are out of my area of responsibility.

Mr. JANKLOW. Okay. If they are, then could you find somebody that could--could you at least take the message back?

And I've got to believe they're doing this. It isn't that they operate in a vacuum over there. They are the best there are.

Dr. WINKENWERDER. Absolutely.

Mr. JANKLOW. This is a way to try and obviate some of these kinds of problems.

Dr. WINKENWERDER. I can just tell you from my exposure to those types of discussions, there is an exquisite level of sensitivity to the issue of how to deal with the issues that you brought up and to avoid any inadvertent or any kind of contamination.

Mr. JANKLOW. Doctor, based on your position, your experience, your background, are you satisfied that we have a good baseline on the troops that are currently in the field or will be going to the field over in Iraq?

Dr. WINKENWERDER. I am.

Mr. JANKLOW. In terms of a medical baseline for them?

Dr. WINKENWERDER. Yes, sir, I am.

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Mr. JANKLOW. And Mr. Roswell, are you satisfied that within the President's budget, the existing budget or the supplemental request, there are sufficient funds to take care of the medical liens, medical needs that are reasonably foreseen--and I realize we could argue about terms--but the medical needs that are reasonably foreseen, that may be necessary for these soldiers, sailors, airmen, Marines when they come home? Or, obviously, in the field, but when they come home?

Dr. ROSWELL. Certainly, based on the current availability of resources we have concerns. But given their high priority, I have no reservation about our ability to--.

Mr. JANKLOW. When you say that, is there any anticipation at all that you will be bumping other people that are currently eligible out of the system or aside to take care of these folks when they come home?

Dr. ROSWELL. That is a contingency that the Secretary of Veterans Affairs, in exercising his statutory authority as mandated by this Congress, would have to consider. So it is possible that if there was an unpredicted demand for care from the Department of Veterans Affairs, by law, Secretary Principi would have to consider other lower priorities of veterans and their ability to continue to enroll in and receive a full health care benefit.

Mr. JANKLOW. Mr. Chairman, can I see that letter for a

second? I guess I have it here, the one that was mailed to you. I am unfamiliar with these letters, until today, that have been talked about. But one of the letters I saw is a letter from Mr. Eldridge--or an E.C. Eldridge, Jr., I am sorry, I assume that is a Mr. Eldridge--to Representative Shays; and in it--I am sorry, one signed by Mr. Eldridge on February 27th of 2003.

And in that one, Mr. Eldridge says to--excuse me--Ms. Schakowsky that every member of Desert Storm will carry at least two--excuse me--every member support near-term operations in Southwest Asia will carry at least two of the new joint service lightweight integrated, the J list suits, and will have an additional two suits in contingency stocks.

Is that the case for the people currently operating in Iraq?

Dr. WINKENWERDER. That is my understanding. Yes.

Mr. JANKLOW. Okay.

Thank you, Mr. Chairman. I have no more questions right now.

Mr. SHAYS. Thank you very much. We are going to put both letters in the record. But the bottom line is, that was the response to my request and also Ms. Schakowsky's.

[The information follows:]

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Mr. SHAYS. Mr. Tierney, you have the floor for a generous 5 minutes.

Mr. TIERNEY. Thank you, Mr. Chairman.

Mr. Chairman, thank you for the long series of these hearings that you've had over the years. I think they have served to benefit the men and women that are there now. I don't think that without having had the hearing on the condition of our suits and things of those materials, that they would have the two new suits; and so I appreciate that, and I am sure their families do.

Mr. SHAYS. It has been a team effort on both sides of the aisle.

Mr. TIERNEY. Doctor, let me--Dr. Winkenwerder, let me ask you for a second:

One of the concerns that we had in doing the homeland security measures and overseeing those was that if there was a contamination, the people responding to that, from medical personnel who oftentimes found themselves unprepared, sometimes exacerbated the situation and completely knocked out an entire medical unit because they hadn't prepared to separate out the contaminated folks, out from the others.

My understanding is that, in the Gulf, most of the medical people, the doctors and nurses sent over there, are Reservists, which would raise the specter that their training is 1 weekend a month or 2 weekends a month and 2 weeks in the

summer; and I would guess that that would probably be barely enough to keep up on their training for medical treatment in the field.

Can you give us some assurance that those Reservists have, in fact, been properly trained to meet what might happen in terms of a chemical or biological attack?

Dr. WINKENWERDER. We expect every service to be trained equally to the Active Duty to take care of those situations.

Mr. TIERNEY. How is that happening if they are getting 1 weekend a month and 2 weeks in the summer, and in that period of time have to keep up with their own medical treatment? How are they getting this additional training? Where are they getting that in a fashion that would give us the comfort that they are really prepared and ready?

Dr. WINKENWERDER. Well, there are a variety of training courses that we offer. And it is part of this overall requirement that I set into place last year that for every medical person in the military health system, professional, that depending upon his or her level, there should be training to deal with chemical and biological events.

And so we expect that. That is a responsibility of each of the services, to provide that training and to ensure that we meet the standards.

Mr. TIERNEY. Have you be monitoring that?

Dr. WINKENWERDER. Yes, we have been.

Mr. TIERNEY. And how much additional training other than that 1 weekend a month and 2 weeks of summer are these personnel getting?

Dr. WINKENWERDER. Well, I had some figures that we recently generated from the three services, and I want to be careful with this, to describe it as accurately as my recollection will allow. But the percentages are in the high double digits now as opposed to the low single digits, what they were a couple of years ago.

So there has been--.

Mr. TIERNEY. Double digits? Single digits? What?

Dr. WINKENWERDER. That means like somewhere between 60 and 80-something percent. And again, there has been an effort to make sure that those that are deploying are the ones that get the training. So when I describe those statistics, that is across the whole system.

Obviously, not everybody is going, so the training has been targeted more towards people that are serving. But I will--I understand the gist of your question and we will try to get back with that information.

Mr. TIERNEY. Would you get that information?

Dr. WINKENWERDER. Yes, sir. We would be glad to.

[The information follows:]

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Mr. TIERNEY. Thank you.

And just, again, because I continue to have concerns about those suits, and even though you've now told me how many suits they have, in my reading anyway, it indicates that that may well not be enough depending on how long this conflict goes.

But you put out the impression at least, that Mr. Kucinich mentioned earlier, about the people being ready; and I am wondering, can you give us the assurance that Secretary Rumsfeld, through Under Secretary Aldridge, was not able to give us? Can you give us the assurance here today that the troops have sufficient equipment to protect them against chemical and biological attacks in quantities sufficient to meet the minimum required levels previously established by the Department of Defense?

Dr. WINKENWERDER. Certainly, from a medical standpoint; and by that I mean the medical countermeasures, the antibiotics, the vaccinations and all of that; those are the issues that come directly under my area of responsibility. The others, my understanding from recent conversations with--Dr. Anna Johnson Winegar, who is the chief responsible person within the Office of the Secretary of Defense for those matters and has testified before this committee and others, has indicated that she believes that we are well prepared on the issues that you have just raised.

Mr. TIERNEY. Well, your impression at least was not contained just to the medical end; it also involved the suits or whatever. Or did it not?

Dr. WINKENWERDER. That is not--and I know from your perspective, as well it should be, you should be concerned about everything, and so I don't want to be bureaucratic here. But--.

Mr. TIERNEY. I appreciate that.

Dr. WINKENWERDER. It is not directly within my area of responsibility. It is another area that does work under Mr. Aldridge. We work ~~real~~ closely, very closely with those people. The responsibility for executing those policies resides within each of those services.

Mr. TIERNEY. Thank you.

And just to finish up my generous 5 minutes, the reason I raised the initial question was that we had an exchange here in committee with Dr. Kingsbury, Nancy Kingsbury, at some point in time; and her answer indicated, to me at least, that in instances of mass casualties she did not believe that the exercises that have been done so far indicated that we could deal with those appropriately.

So whatever assurances you could give the committee in --returning to that in terms of medical personnel being ready would be greatly appreciated.

Dr. WINKENWERDER. We will do that.

[The information follows:]

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Mr. TIERNEY. Thank you.

Mr. SHAYS. Thank the gentleman.

We are going to do a second round here, and I just want to ask--so we can close up the issue of the questionnaire, I want to know why our men and women aren't given physicals when they go into battle, so that we know. What is the logic of that?

Mr. JANKLOW. Aren't given what, sir?

Mr. SHAYS. Aren't given physicals. They are given questionnaires, but they aren't given physical examinations.

Dr. WINKENWERDER. I think, Mr. Chairman, that the logic is that a hands-on physical examination yields not a great deal of information in terms of the baseline health status of young, healthy individuals. And far more important and relevant is a series of questions that are asked that can go into greater detail if a flag goes up that indicates that there is some problem with that person's health.

Mr. SHAYS. I could hear the--first off, I am not going to concede that we didn't intend that they weren't going to have physicals. So I understand your doing the questionnaires, and I understand when we talk about a medical examination versus a physical examination, you have decided that you have some flexibility there.

But what about the Reservists and the National Guard folks who simply, you know, might be eating a little

differently, might--you get my gist. Why wouldn't they have physicals? They might be older. They might not have been active for a while. Why treat them all the same?

Dr. WINKENWERDER. Why treat them all the same?

Mr. SHAYS. Why treat them all the same? Why not have a little bit more of an interest in giving a physical to someone who may not have been in the Active Service?

Dr. WINKENWERDER. You raise a good point. I think it is something we could certainly take a look at.

Dr. Kilpatrick.

Dr. KILPATRICK. If I could, for the Reservists that are called to Active Duty, there is a more stringent process put in place to look at them, having physical examinations, their periodic physical examinations.

For Reservists under 40, they need to have one every 5 years; over 40, every 2 years. I think there is a recent GAO report that showed that people were not meeting the mark--I mean, the numbers were terrible--on doing that. So when people are called to Active Duty at that mobilization center, if they have not had a physical within the last 5 years for under 40 or the last two years over 40, they have to have a physical before they go, so they are caught up.

Mr. SHAYS. Why not at least draw blood and why not do that?

Dr. KILPATRICK. And I think the drawing of blood is--we

do make sure that everyone has an HIV screening sample done within the previous 12 months prior to deployment. That serum sample is banked in a serum bank. It is kept permanently. There is no sort of portfolio of tests to do on a serum sample, but that is kept in the eventuality there is an exposure, either recognized or unrecognized, and then a determination of a set of tests that could be done. So the serum sample is saved, but there is no testing done, prior to leaving, for levels of any agents.

Mr. SHAYS. Dr. Roswell, how much involved were you on--how are you involved in the predeployment questionnaire? How much involvement did you have in this questionnaire?

Dr. ROSWELL. Relatively little, Mr. Chairman.

Mr. SHAYS. Does relatively little mean, really, I didn't have much involvement at all?

Dr. ROSWELL. The survey was shared with us. We have effective communication through the Health Executive Council that Dr. Winkenwerder and I cochair. So there is an active sharing of information.

Mr. SHAYS. But this was basically designed by DOD, Dr. Winkenwerder?

Dr. KILPATRICK. Yes.

Dr. WINKENWERDER. Designed in 1997.

Mr. SHAYS. 1997. Okay. We have a letter that Principi--Principi; I'm sorry, I went to a college called

Principia, so I have a bit of a problem with that name--where the Secretary had written. And he said--and this is a letter he drafted to Mr. Rumsfeld on--Secretary Rumsfeld on February 14th of this year; and the second page says, "In the event of hostilities, VA further requests more extensive postconflict health data. Within the first month after hostilities cease, VA recommends administration of a detailed postwar health questionnaire to accurately document the health status and health risk factors and health in Gulf War troops immediately after the conflict." .

Can you explain that a little to me?

And, Dr. Winkenwerder, can you respond?

Dr. ROSWELL. I think what Secretary Principi was asking for was to get--to get risk assessment and self-reporting--.

Mr. SHAYS. Excuse me. Let me just say for the record, with just three members, I am going to roll to a 10-minute question. So you'll have 10, and we'll go from there.

Thank you. Go ahead.

Dr. ROSWELL. Our concern is that particularly with Reservists and National Guard, when they are demobilized, the immediate concern--and it's true of Active Duty as well--is to get home to family and loved ones. But unlike the Active component, when the Reservists are demobilized, they may be lost to follow-up, and it may be difficult to get information.

We learned, painfully so, in the Gulf War that when we surveyed service members who had separated from military service months or years after their service in the Gulf War, that there was a high level of what we would call "recall bias." they don't really remember the specifics, it is hard to recall a specific date. A service member might not remember an actual grid coordinate or an actual physical location.

So I think what Secretary Principi was asking Secretary Rumsfeld was that, in the event of possible exposures, we get as much information as possible at the time military members are demobilized and separated from service. That would help us evaluate possible symptomatic exposures and health consequences that might have--.

Mr. SHAYS. So there's logic to doing this.

Let me just ask, Dr. Winkenwerder, do you--we had in 1997, you have this--developed this questionnaire we are using today.

Do you have a postsurvey questionnaire that was done in 1997, or is that still a work in progress?

Dr. WINKENWERDER. That was developed in the same time frame.

Mr. SHAYS. We are asking that that questionnaire be updated and improved.

Dr. Roswell?

Dr. ROSWELL. The postdeployment survey that Dr. Winkenwerder speaks of would certainly be helpful. Obviously, we'd seek more complete information if there was a documented or suspected exposure.

Mr. SHAYS. It's just a two-page document?

Dr. ROSWELL. Correct.

Mr. SHAYS. It doesn't even look as extensive. I guess it's the same as--both are two page.

I would hope, Dr. Winkenwerder, that you will give tremendous consideration to Principi's letter and request, and absolutely determine that our troops, shortly after--not after they are sent back home, but you know, a month or two after the conflict ends, that they are going to have this kind of questionnaire.

And I am going to--I am seeing the nodding of heads. I would love to know if you could put something in that we could transcribe here.

Dr. WINKENWERDER. Yes. Well, I share the objective of getting accurate information in a timely way.

Mr. SHAYS. And do you believe that maybe a more than just two-page questionnaire would be helpful?

Dr. WINKENWERDER. I have already initiated an effort to reassess this survey tool to see if it collects all the information that we think it ought to collect.

Mr. SHAYS. Do you give some weight to the Secretary of

Veterans Affairs, who ultimately has to deal with this, that--.

Dr. WINKENWERDER. Oh, absolutely.

Mr. SHAYS. Okay.

Dr. WINKENWERDER. Yeah, absolutely. So I've, number one, done that.

And secondly, ideally, if we could collect that information even before people come back to the United States, it would be great. Logistically, we are still looking at that. Obviously, we have to have a lot of cooperation and assistance from many, many people to--.

Mr. SHAYS. And you may have to do some physicals. You may have to add more than physicals to the questionnaire, and you may have to have more of these folks actually take a physical when they leave.

Dr. WINKENWERDER. Well, I would expect, with a good detailed questionnaire that whenever people gave any reason for concern, they would then be very carefully evaluated.

Mr. SHAYS. Okay.

Mrs. Maloney.

Mrs. MALONEY. Thank you, Mr. Chairman. I would like permission to place in the record an article written by Judith Coburn entitled Suited for War, and it is very thought provoking. In it, she alleges--.

Mr. SHAYS. Without objection, that will be put in.

Mrs. MALONEY. Thank you. In it, she alleges that it took a four-year struggle of Gulf War veterans from Georgia before they got the Pentagon to declassify documents which revealed that Iraq's stocks of sarin gas stored in Khamisiyah had been blown up, and that roughly 140,000 American troops were exposed.

I realize, Dr. Winkenwerder, this did not happen on your watch, but I fail to understand the mentality or the mind frame of a department that would withhold valuable information on the exposure to chemicals that could hurt people.

And I understand this was not on your watch, but if you can find any documentation on what they were thinking about or what, in their minds, they thought they couldn't reveal to our men and women, that they may have been exposed, I would love to get that back in writing.

But my question--and Ms. Coburn further goes on.

Mr. SHAYS. Let me be clear. What do you want back in writing?

Mrs. MALONEY. Why the Pentagon fought the release of information on men and women being exposed to sarin gas when they knew they were exposed in that particular area.

Mr. SHAYS. The record will note that they acknowledged that our troops were exposed, before our hearing, at a press conference. Then there was a question as to how many troops

were ultimately exposed, and the numbers kept going up.

And so what would be helpful is if, in fact, additional information was held and for how long and why. And that will be--it is just not a wish, it is a request that--Dr. Kilpatrick, you are nodding your head--you will get back to us on.

Dr. KILPATRICK. Yes. There is a great deal of information. We will pull out all together and provide it.

[The information follows:]

******** COMMITTEE INSERT ********

Mrs. MALONEY. She further states that 148 Americans died in the war, but that roughly 160,000 have fallen ill; and that 11,000 have died since the Gulf War--much higher than other men and women in the military--and that they have collected a series of 57 symptoms for which there is no known cause, which is the Gulf War Syndrome.

I would want to ask what we are doing to protect the health of the men and women that were exposed and the possibility, God forbid, that they may be exposed yet again. And I am the cochair of the Parkinson's Disease Task Force, along with Fred Upton; it is a bipartisan effort. And my father suffered from Parkinson's.

But it has been reported that some of the Gulf War veterans have suffered symptoms similar to Parkinson's. And each year we have been working with the Defense Department, and we have received funding for Parkinson's research on neurotoxin exposure, seeing if that is a reason for the brain damage that causes Parkinson's. But I would argue that, likewise, it may be a study for what we can do to help the men and women that may have been exposed to chemicals.

So my question right now is more of a proactive one of, what are we doing in research?

As I understand it, we have no cure for Gulf War Syndrome. And what are we doing to find--are we spending some of our research dollars in trying to find a cure for

neurotoxin disease that may be caused by the sarin gas or other things? What are we doing? I am very thankful to the Department of Defense for funding the Parkinson's research.

My question is, is this likewise connected to the Gulf War Syndrome?

Dr. WINKENWERDER. To your general question of what are we doing? We are continuing to fund with millions of dollars ongoing research into many of these questions that you have raised. As I alluded to earlier, it's difficult to determine with the levels of certainty that one would like in this case, if one is talking about evaluating these individuals that served, when the baseline of information and what was collected and what people may or may not have been exposed to is not good.

The information is not good, so--by definition, to do good research, you need good information. That shouldn't prevent us from funding additional research, as we have done, to look at some of these questions of what would low levels of exposures do to laboratory animals. Certainly we would never do this to any individual on an experimental basis. But studying what happens with animals and looking at some of these things is very important.

Mrs. MALONEY. Specifically, is the Parkinson's research that you are funding--and I thank you for that research. Is that connected to the Gulf War Syndrome?

Dr. WINKENWERDER. I am going to turn to Dr. Kilpatrick.

Dr. KILPATRICK. Let me just address it. It is being pursued in two directions.

One is a clinical basis, looking at people; and then that is very tightly tied to a program looking at chemical nerve agents in particular and the effects that they have on brain function. And there are projects funded at $5 million a year over the next 3 years; 1.5 million is looking at repeated low-level exposures of animals to sarin nerve agent, to look at long-term health consequences. That is very applicable to what Gulf War veterans' concerns are.

The other part of the money each year is spent toward what we call the high end of low-level exposure, below symptomatic response to nerve agents, one exposure, and then seeing what are the physiological responses.

And those data from those research sets are really very closely shared with people looking at Parkinson's disease, because they are really looking at the same pathway potentially as far as disease cause.

Dr. ROSWELL. If I may respond to that from a combined perspective.

Since the Gulf War, over $200 million in federally funded research has been focused on possible causes for Gulf War Syndrome. I would like to set the record straight.

One of those studies has looked at death rates in

MEK

veterans in the Gulf War, and in fact, the overall death rate for veterans who served in the Gulf War is not increased compared to their military counterparts who were deployed outside the theater of operations. If you look at specific-cause mortality in veterans who served in the Gulf War, there is a very slight increase in death due to trauma, such as automobile accidents. But other than that, the mortality rate is not increased in any subcategory, and the overall mortality is not increased.

And I certainly wouldn't want to create a fear for the men and women currently serving in Iraq.

Let me point out that Parkinson's disease is one of several neurodegenerative diseases that DOD and VA are currently studying. VA recently funded the creation of a neuroimaging Center of Excellence for neurodegenerative diseases to look not only at Parkinson's but also other diseases, even when unpublished data suggested that there might be an increase in a degenerative disease known as amyotrophic lateral sclerosis, or Lou Gehrig's disease.

Secretary Principi moved quickly to presumptively service-connect veterans who suffered from that illness and served in the Gulf War, so that they received disability compensation.

I would also point out that 160,000 veterans of the Gulf War have received approved disability claims. But most of

those claims are for diseases that we would expect to see in a military age population, and it is a relatively small number for undiagnosed illnesses or the Gulf War Syndrome you spoke of.

Mrs. MALONEY. When you mentioned the clinical trials, are you doing them on our veterans? Are we tracking our veterans and seeing if--particularly those that we know were exposed to sarin gas? That would be helpful to see, because some of them apparently--I am talking to doctors that treat Parkinson's. They have told me that they are developing Parkinson's-like symptoms.

Dr. ROSWELL. We have extensively reviewed literature for symptomatic exposures to the organophosphate, which is the class of compounds that sarin nerve gas falls into. The study suggests that there is cognitive impairment in people who suffer symptomatic exposures, but I am not aware of evidence that conclusively links any kind of organophosphate or nerve agent exposure to Parkinson's disease specifically.

Some investigators have reported a possible neurodegenerative disorder that involves part of the vasoganglia, which are structures that are affected in Parkinson's, but in a way different than in Parkinson's disease, which is why we've funded the neuroimaging center.

Mrs. MALONEY. Where is the neuroimaging center?

Dr. ROSWELL. Actually, there are several within the VA.

There is one in San Francisco; there is--a final selection for the designated center has not yet been made, however.

Mrs. MALONEY. Well, thank you for investing in research for coming up with some cures. And thank you for your testimony. My time is up.

Mr. SHAYS. We have just two more members who will ask some questions, and then we are going to get to the next panel.

Mr. Janklow.

Mr. JANKLOW. Thank you very much, Mr. Chairman.

Help me, if you could. With the testimony--the hearing is about lessons learned from the Gulf. My question is, both of you in your capacities, you, Dr. Roswell, and you, Dr. Winkenwerder, have you looked into the history of why was this so secret so long? With everybody clamoring for information, why did it take so long to get the information out? Why did it have to be dragged out of people? What was the reason for the mystery?

I guess--have you ever been able to find out, or have you ever looked as to the reason for the mystery? It couldn't have been national defense secrets.

Dr. WINKENWERDER. I can't give you a good answer. I will give you the best answer I know, and that is that in many cases it took months and even years for symptoms to develop with people. And that, combined with the poor record

base, made it very difficult to do research or to even develop good, plausible mechanisms, causal-related mechanisms.

Mr. JANKLOW. Have those problems been solved?

Dr. WINKENWERDER. In my judgment, we have a far superior baseline of information. We have a far improved recordkeeping system. We have a far improved ability to surveil and actually keep records in the theater. We have these pre- and postdeployment assessments. So our information base, by all accounts, should be far, far better in our current situation.

Mr. JANKLOW. Doctor, I believe you said you have been in your position about 18 months.

Dr. WINKENWERDER. Yes, sir.

Mr. JANKLOW. And for you, is there anything, at least at this point in time in your tenure in this position, where we have got a lesson we haven't learned?

Dr. WINKENWERDER. Well, I hope we don't have one that I am not attending to.

Mr. JANKLOW. Are there any--do you know of any that concern you or that we ought to be concerned about?

Or you Dr. Roswell?

Either one of you, are there any lessons we haven't learned?

Dr. ROSWELL. If I could, I think the Gulf War was an

unprecedented conflict. The breadth and nature of military occupational exposures had never been experienced by our men and women in any prior conflict. So part of the delay, if you will, the confusion--I think, in retrospect, it is fair to say there was some confusion about exposures and possible health consequences--was because we didn't recognize that a vast number of unprecedented exposures could be factors: the anthrax vaccine, the pyridostigmine bromide that was used, the dense oil fire smoke, the fine particulate sand in the desert, the use of petroleum products to cut down on the blowing sand, the use of permethrin and DEET to protect people from insects--there were so many exposures--the use of depleted uranium as both an armour-piercing munition and a firearm plate, even chemical agent-resistant coating paint, which was applied to vehicles to make them resistant to chemical agents--were just some of the possible exposures that were investigated methodically, consistently over time to try to ferret out possible causes for the illnesses we saw in Gulf War veterans.

And I think that, to me, if there is a lesson learned, it is that we have learned that all of these exposures, singly or in combination, as has been pointed out in this hearing, could be factors in the development of illness. Certainly, every major conflict that U.S. Men and women have served in has yielded unexplained illnesses.

But that doesn't obviate our need to methodically and thoroughly investigate each and every exposure. And that is why we are committed to do that, and I think that is the partnership that VA and DOD, through the Deployment Health Working Group, are vested in right now.

Mr. JANKLOW. Dr. Kilpatrick, are there any unlearned lessons that you know of lingering from the Gulf War?

Dr. KILPATRICK. I think one of the hardest ones is communication. It doesn't matter how good a job you do, you can always do it better.

And I think one of the issues that we are working at very hard now is to make sure that leaders in the field are communicating to their troops that they are concerned about these various exposures, their health. They are concerned about documenting where they are. They are concerned about making sure they have that access to health care when they come home--I think DOD and VA share the same concern for those who are getting off Active Duty; they will be looking perhaps to the VA for health care--that they understand that, in fact, there is the ability for them to have 2 years of health care coming out of a combat zone now. That was not present after the Gulf War in 1991. And I think that that is--getting that communicated to people, so they know they have that access to health care, is so important.

So I think that that is one of the areas where, as good a

job as I think we are doing, we always need to look to say, how can we do it better. And I think doing that, through even this hearing, is very helpful to those men and women who are serving today.

Dr. WINKENWERDER. And if I might add to that to say, you know, you never know when you haven't learned a lesson until--there are many times you don't until you've learned it, which to me speaks to the need culturally to have an open mind, be open to learning things that you didn't know before.

And so if there is one thing that I would continue to hope to convey to our people it is a continued vigilance about different sources and causes of illness and ways to improve. It is sort of a culture of learning and getting better.

Mr. JANKLOW. Assuming we have the baseline data that we need for the current war that we are in, recognizing that our troops could be exposed to biological or chemical warfare, do we have the systems in place?

I mean, that is the key thing. Do we have the systems in place to be able to get the information about the individuals and about the chemical or the agents or the toxins that are being--that they have been exposed to, so that we will have the database of information to address it without all the types of--new types of frustration that we will have to go through in order to find out whether or not there are or

aren't legitimate reasons for illnesses or problems that people have after the war?

Am I making sense to you?

Dr. WINKENWERDER. Yes.

Mr. JANKLOW. Do we have a system in place, is what it comes down to. I realize we had no history before the Gulf War. We now have a history.

Dr. WINKENWERDER. I believe we do have the system in place.

Mr. JANKLOW. Is there anything we can do to make it better?

Dr. WINKENWERDER. Yes.

Mr. JANKLOW. What?

Dr. WINKENWERDER. One of the things that we can do to make it better is to ensure that there is 100 percent compliance with all the policies and all the procedures, the training we have talked about.

Mr. JANKLOW. Have those orders gone out to the military?

Dr. WINKENWERDER. Absolutely.

Mr. JANKLOW. Is there any reason that the military would have for not following orders from above that are lawful?

Dr. WINKENWERDER. No. I have no reason to believe that people have not taken this issue extremely seriously.

Mr. JANKLOW. Do they understand that if they violate direct, lawful orders from a superior, that it sometimes is

far more serious in the military than it is in civilian life?

Dr. WINKENWERDER. Yes. I think there is a good understanding of that.

Mr. JANKLOW. Those are all the questions I have, sir.

Mr. SHAYS. Thank you.

Mr. Tierney.

Mr. TIERNEY. Thank you. I have only a follow-up question.

We know that this 2004 VA budget, Dr. Roswell, has several provisions that are going to restrict the ability of certain classifications of veterans, Priority 7 and Priority 8, to get treated and to get the cost of care covered--I can't get this thing to stop moving up and down.

Isn't that one of the lessons we've learned, though? If we have incidents that are not really showing signs of symptoms or illnesses for several years after people get out of the service, being covered for the first 2 years may not be sufficient. And haven't we learned through some of the Gulf War Syndrome incidents that it can be any number of years before people start coming down with these symptoms?

So having learned that lesson, we put out a budget that still doesn't seem to address these people's concerns.

What are your concerns about that, and what can we do about the fact that some of these people may not exhibit symptoms in the first couple of years? And how is the VA

going to deal with those people without excluding them from coverage?

Dr. ROSWELL. Well, certainly one way to do that is to authorize special access for care for people who have illnesses that occur following a conflict.

We actually had that authority that just expired in 2002 for veterans of the Gulf War. It would be obviously, depending upon the outcome of the current conflict, appropriate for this Congress to consider special authorization for priority care for veterans who have served in this conflict.

The 2 years is a minimum. It would certainly continue beyond that if an identified need were discovered during that period or if an illness, injury, or disability associated with military service were identified that led to a service connection.

Mr. TIERNEY. I think your first recommendation is probably one that we ought to look into, and that is making sure that we provide some sort of flexibility or ability to cover those for people that may be coming out of this conflict, and I appreciate that.

Mr. Chairman, I have no other questions at this time. I want to thank our witnesses for their thoughtful answers and for their assistance here today. Thank you.

Mr. SHAYS. Thank the gentleman. Let me just do a few

little minor points for the record.

Dr. Roswell, we are looking at VA data and reports on mortality in the Gulf War. And its recent reports, based on VA data, have been late. There was one report that showed kind of a real spike in deaths, and it was called back and we are curious about that.

So we are going to invite the VA back to have a dialogue about this, but I just kind of feel your comment about not showing much difference is something that this committee has a big question with.

And I would also just say, Dr. Winkenwerder, that I have some specific questions about the status of the Armed Forces Radiobiology Research Institute and their work on a drug to counteract the effects of radiation exposure.

RPTS BULKLEY

DCMN BURRELL

Mr. SHAYS. And we're going to second these questions in writing to your office and ask that you respond. I don't think we need to take time to do that now, we think.

Dr. WINKENWERDER. We'd be glad to do that.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. SHAYS. And also say, Dr. Hyams, you have the biggest challenge here, and I have a theory and it never fails me that the person who says the least has the greatest contribution at the end to make. So I'm going to just ask--no, I'm not going to do it quite that way. But I'm going to say to you that I would like you to put on the record anything that you think needs to be put on the record or any observation that you would like to put on the record, and then we'll get to the last panel.

And Dr. Hyams, I would also invite you as well. I'm not being facetious. I know all four of you have expertise here, and we didn't ask Dr. Roswell as many questions so you didn't need to jump in, but I'm happy to have all four of you make any final comment. I'll start with you, Dr. Kilpatrick.

Dr. KILPATRICK. Well, I think that the Department of Defense is very focused from the lessons learned in the Gulf on how do we better take care of our men and women in harm's way today. I think the Force Health Protection Program is that cascade effect of programs that will protect health. It does depend on good leadership and cohesive units. We believe we have that that we see that in action today, and it is our duty to make sure from a medical standpoint that those men and women have their health concerns addressed, and our medical department stands by waiting to make sure that their health concerns, whether they are related to the deployment

or any other concern, get addressed with facts about exposures we know occurred.

Mr. SHAYS. Thank you.

Dr. WINKENWERDER. Mr. Chairman, I'd just say we appreciate the opportunity to be here today. I think this has been a productive exchange of information. I hope you've found it that way and useful.

My first comment is just to say that I deeply appreciate the sacrifice that our men and women in uniform are making, and I also deeply appreciate the outstanding job that our medical people are doing. I think we've seen from the TV reports and all just the incredible job they're doing. They've made us all very proud.

We are absolutely committed to trying to protect our people who are taking on a very challenging situation, a brutal regime that has terrible weapons. We've done everything that we know we can do to protect them. We will continue throughout this conflict and after the conflict is over to ensure that we look after people's health care needs and that we do right by them for the good service that they've done. So I'm committed to that.

Mr. SHAYS. Thank you.

Dr. ROSWELL. Mr. Chairman, let me begin by thanking you for your leadership over the last decade in moving our government closer to a more full and complete understanding

of the day. You have the floor and you're asking great questions. I'm done.

Dr. MOXLEY. In our written statement, we--.

Mr. SHAYS. Could I just thank--before--I'm interrupting. I'm sorry. I just wanted to thank Dr. Winkenwerder for staying here and having the courtesy of listening to their points. I'd like to do a little connection between you and them and also to point out Dr. Kilpatrick is here and also Dr. Hyams as well, and thank all three of them for showing you the courtesy and also learning from what you might say. That's very helpful of you.

Thank you.

Dr. WINKENWERDER. Thank you. We're glad to have more interaction here.

Mr. SHAYS. We'll make sure that happens. Thank you.

I'm sorry to interrupt.

Dr. MOXLEY. Well, I was trying to come back to some sort of answer to your question. I was going to say in our written statement we recapitulate our recommendations. I mean, it would be a fairly long list of inquiries, but one could ask whoever is responsible has this been implemented. I don't know that going over it I could improve upon it, and they are in the written record.

Mr. JANKLOW. Sir, after this report was submitted to the Defense Department, did you ever hear back anything?

DMMC Control #
2003167-0000017

(24)

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

JUN 6 2003

Honorable Mark D. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. McClellan:

The Department of Defense continues to be asked questions about the determination by the Food and Drug Administration that Anthrax Vaccine Adsorbed (AVA) is licensed for the prevention of anthrax disease that results from any of several possible routes of exposure.

In an effort to answer conclusively questions about this, the Conference Report accompanying the Department of Defense Appropriations Act, 2000, H. Conf. Rept. No. 106-371, p. 254, stated: "The Department is directed to enter into a contract with the National Research Council to independently study the effectiveness and safety of the anthrax vaccine," including "inhalational efficacy of the vaccine against all known anthrax strains."

The Institute of Medicine (IOM) Report, "The Anthrax Vaccine: Is it Safe? Does it Work?" 2002, responded. Chapter 3, "Anthrax Vaccine Efficacy" (copy attached), analyzed the scientific evidence and concluded with the following finding:

> Finding: The committee finds that the available evidence from studies with humans and animals, coupled with reasonable assumptions of analogy, shows that AVA as licensed is an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by any known or plausible engineered strain of *B. anthracis*.

In its analysis and conclusion about anthrax vaccine efficacy, the IOM Report accurately reflects the understanding of the Department of Defense of the scientific evidence and information. I ask if you can confirm that it also reflects the FDA's position. Thank you for your attention to this request.

Sincerely,

William Winkenwerder

William Winkenwerder, Jr., MD

Attachment

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

DMMC Control #
2003213-0000002

25

ACTION MEMO

July 31, 2003 1000 A.M.

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, (Force Health Protection and Readiness)

SUBJECT: Report to Congress on Separations of Members of the Armed Forces as a Result of a Refusal to Participate in the Anthrax Vaccine Immunization Program (AVIP) for CY 2001 and CY 2002.

- Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Secretary of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the AVIP.

- TAB A contains the transmittal letters for the Chairmen and Ranking Members of the SASC and HASC.

- TAB B is the report for 2002. During the January 1, through December 31, 2002, reporting period, separation and appeal procedures ended for one servicemember, who was subsequently separated from the Armed Forces.

- TAB C is the report for 2001. During the January 1 through December 31, 2001, reporting period, separation and appeal procedures were completed for two servicemembers who then were separated from the Armed Forces.

- This report has been staffed and coordinated. The Joint Staff revalidated all numbers with the respective Services.

COORDINATIONS: TAB D

RECOMMENDATION: Sign letters at TAB A.

Attachments:
As stated

Prepared by: CDR [redacted] DHSD, [redacted] PCDOCS: 53225

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

Honorable John W. Warner
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Secretary of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

During the January 1, through December 31, 2002, reporting period, separation and appeal procedures ended for one servicemember, who was subsequently separated from the Armed Forces. During this same period, 72,744 servicemembers received 155,886 doses of licensed anthrax vaccine.

During the January 1 through December 31, 2001, calendar year, two servicemembers were separated as a result of refusing to participate in the AVIP. During the same timeframe, over 28,000 servicemembers participated in the AVIP, receiving over 119, 000 doses of licensed anthrax vaccine.

As of May 25, 2003, over 875,107 servicemembers have participated in the AVIP, receiving over 3,050,671 doses.

A similar letter has been provided to the Chairman and Ranking Member of the House Armed Services Committee.

Sincerely,

William Winkenwerder Jr., MD

Enclosure

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

Honorable Carl Levin
Ranking Member
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Senator Levin:

Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Secretary of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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Sincerely,

William Winkenwerder Jr., MD

Enclosure

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

Honorable Duncan Hunter
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Secretary of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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Sincerely,

William Winkenwerder Jr., MD

Enclosure

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

Honorable Ike Skelton
Ranking Member
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Skelton:

Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Secretary of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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A similar letter has been provided to the Chairman and Ranking Member of the Senate Armed Services Committee.

Sincerely,

William Winkenwerder Jr., MD

Enclosure

DEPARTMENT OF DEFENSE
REPORT ON
SEPARATIONS THAT RESULT FROM A REFUSAL
TO PARTICIPATE IN THE ANTHRAX VACCINE
IMMUNIZATION PROGRAM

January 1, through December 31, 2002, Separations

Service	Separations	Component	Rank	Total
Army	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Navy	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Air Force	1	Active	E-4	1
	0	Guard	n/a	0
	0	Reserve	n/a	0
Marines	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Services Total ----------→				1

(January 1, through December 31, 2002)

DEPARTMENT OF DEFENSE
REPORT ON
SEPARATIONS THAT RESULT FROM A REFUSAL
TO PARTICIPATE IN THE ANTHRAX VACCINE
IMMUNIZATION PROGRAM

January 1, 2001 through December 31, 2001 Separations

Service	Separations	Component	Rank	Total
Army	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Navy	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Air Force	0	Active	n/a	0
	1	Guard	0-4	1
	0	Reserve	n/a	0
Marines	1	Active	E-3	1
	0	Guard	n/a	0
	0	Reserve	n/a	0

Services Total ——————————————→ **2**

(January 1, through December 31, 2001)

Subject: Report to Congress on Separations as a Result of Refusing to Participate in the AVIP.

COORDINATION

	Comments
OSD, General Counsel	Concur
Assistant Secretary of Defense (LA)	Concur
Director, Military Vaccines Agency	Concur
Director, Joint Staff	Concur

Coordination of Proposed Report to Congress on Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
OSD, General Counsel	(b)(6)		as revised 6/13/23
Assistant Secretary of Defense (LA)			
Director, Military Vaccines Office			
OSD (OGC)			
Dir, Joint Staff			

The Honorable Duncan Hunter
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Secretary of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

During the January 1 through December 31, 2002, reporting period, separation and appeal procedures ended for one Service member, who was subsequently separated from the armed forces. During this same period 72,744 Service members received 155,886 doses of licensed anthrax vaccine.

During the January 1 through December 31, 2001, calendar year, three Service members were separated as a result of refusing to participate in the AVIP. During this same timeframe over 28,000 Service members participated in the AVIP, ~~with over~~ receiving more than 119, 000 doses of licensed anthrax vaccine.

As of May 25, 2003, over 875,107 Service members have participated in the AVIP, receiving with over 3,050,671 doses.

I have enclosed the proposed Report to Congress on Separations that Result from a Refusal to Participate in the AVIP. A similar letter has been provided to the Chairman and Ranking Member of the House Armed Services Committee.

Sincerely,

William Winkenwerder Jr., MD

Enclosure

these look like exact numbers. Do you mean to say "over"? Should be "more"

DEPARTMENT OF DEFENSE
REPORT ON
SEPARATIONS THAT RESULT FROM A REFUSAL
TO PARTICIPATE IN THE ANTHRAX VACCINE
IMMUNIZATION PROGRAM

January 1 through December 31, 2002

Service	Separations	Component	Rank	Total
Army	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0

Note: One separation occurred in 2003 and will be reported in the 2003 timeframe.

Navy	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Air Force	1	Active	E-4	1
	0	Guard	n/a	0
	0	Reserve	n/a	0
Marines	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0

Services Total ——————————→ 1

Coordination of Proposed Report to Congress on Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
OSD, Office General Counsel			
Assistant Secretary of Defense (LA)			
Director, Military Vaccine Agency	✓		(b)(6) 7/9/03
Dir, Joint Staff			

Coordination of Proposed Report to Congress on Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
OSD, General Counsel			
Assistant Secretary of Defense (LA)			
Director, Military Vaccines Office			
OSD (OGC)			
Dir, Joint Staff			

JUN-13-2003 09:37

OSD Legislative Affairs
Correspondence Control Cover Sheet

Document Number: 5914 **SecDef/DepSec Coordination** ☐ **Classified Coordination:** ☒

Date of Correspondence: 04-Jun-03 **Assigned Due Date** 16-Jun-03 **Date Received** 12-Jun-03

Subject: Coordination of Proposed Report to Congress on Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program

CCD Control Number: **Member of Congress:** Levin Carl

Originating Agency: Health Affairs

Agency POC: CDR (b)(6) **Fax#** (b)(6) **Agency POC Telephone:** [redacted]

Routing List: **Transfered T** **Date Transfered:** 6/12/03

Action Officer (b)(6) (LtCol) Concur / Non-Concur

Comments:

Routing List: **Transfered To:** **Date Transfered**

DASD: Concur / Non-Concur

Comments:

Routing List: **Transfered To:** **Date Transfered**

ASD LA: Concur / Non-Concur

Routing List: **Transfered To:** **Date Transfered:**

Comments:

[redacted]

Picked up by: _____
(PRINT NAME)

_____
(SIGNATURE)

Office of the Assistant Secretary of Defense
for Legislative Affairs
Room 3D932
1300 Defense Pentagon
Washington, D.C. 20301-1300

Facsimile Cover Sheet

To:	(b)(6)
Tele:	
Fax:	(b)(6)
From:	(b)(6)
Tele:	
Fax:	
Date:	
Pages including this cover page:	1 of 3

Remarks: Coordination # 5914

THE JOINT STAFF
WASHINGTON, DC

Reply ZIP Code:
20318-0300

DJSM-0695-03
30 July 2003

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

Subject: Coordination of the Proposed Report to Congress on the Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program (AVIP)

1. Thank you for the opportunity to review the draft report[1] to Congress regarding the number of separations resulting from refusal to participate in AVIP. The Services verified the accuracy of separations reflected in your proposed report. The statistics are correct except the Marines had one versus two separations in calendar year 2001.

2. We concur in the report subject to incorporation of the following changes:

a. ASD(HA) letter to Chairman Warner, third paragraph, first sentence. Change to read: "During the 2001 calendar year, January 1 through December 31, two Service members were separated as a result of refusing to participate in the AVIP."

b. Enclosure, second page, Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program, January 1, 2001 through December 31, 2001, Service column, Marines, first line. Change to read: Separations "1," Rank "E-3," and Total "1."

3. The Joint Staff point of contact is Major [redacted] USAF; J-1/PRD; [redacted]

JAMES A. HAWKINS
Major General, USAF
Vice Director, Joint Staff

HA/TMA Document Profile

DMMC Control #
50272 2003318-0000015

26

Subject:	Smallpox Vaccine Adverse Event Follow-up of Guard and Reserve		
Author:		**Congressional Name:**	
Date of Document:		**Input By:**	(b)(6)
OSD # :		**Profiler's Directorate**	C&PP
PR # :		**Response Signed By:**	
Organization:		**Dt Response Signed:**	
Department:		**Dt Documents Mailed:**	
Assigned To:		**Doc Type:**	MEMO
Action Officer:		**Application:**	MS WORD
Prepared For:		**Previous Documents:**	
Suspense Date:		**Related Documents:**	57287
Coord Office(s)			

Notes: 11-13-03 Fwd to FHP/R for coordination by DASD(C&PP). (PLT)

Beneficiary Info

Beneficiary Name:	
Address 1:	
Apartment #	
Phone #	
Email Address:	
City:	
State:	**Zip**

History
Created: 5/27/2003 (b)(6)
Edited: 11/10/2003
Status: Available

Retention Schedule
Type: Archive
Retention Days: 365

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Access Control
☒ **Secure Document**
☒ **Enable Content Searching**

ACTION MEMO

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: David Tornberg, DASD Clinical and Program Policy

SUBJECT: Smallpox Vaccine Adverse Event Follow-up of Guard and Reserve Component Personnel

- The ASD(HA) should sign the memo at TAB A.

- Smallpox vaccine has been associated with new onset myopericarditis. A program for initial and long-term follow-up of individuals diagnosed with smallpox vaccine associated myopericarditis has been established (TAB B). The longer-term morbidity among these individuals will significantly impact future decisions on smallpox vaccination. As Guard and Reserve component personnel are demobilized, it is important that appropriate follow-up continue to take place.

- The memorandum at TAB A directs Line of Duty (LOD) statement for vaccinated personnel with cardiac complications. Those individuals requiring medical treatment/evaluation should be retained on Active Duty pending resolution of the medical condition or completion of the physical disability evaluation. The memo was coordinated with Service M&RA and other offices (TAB C) with no objections noted.

RECOMMENDATION: That the ASD(HA) sign memorandum to M&RA's at TAB A.

COORDINATION: TAB D

Attachments:
As stated

Prepared by: LtCol (b)(6) C&PP, (b)(6) PCDOCS# 50272

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT: Establishment of Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis

REFERENCES:

1. Deputy Secretary of Defense Memorandum, "Smallpox Vaccination Program," September 30, 2002
2. Under Secretary of Defense for Personnel and Readiness Memorandum, "Policy on Administrative Issues Related to Smallpox Vaccination Program (SVP)," December 13, 2002
3. Assistant Secretary of Defense for Health Affairs Memorandum, "Clinical Policy for the DoD Smallpox Vaccination Program (SVP)," November 26, 2002

Myopericarditis has historically been associated with vaccination for smallpox (vaccinia virus). Until recently, it has been a rare or unrecognized event after vaccination with the currently utilized strain of vaccinia virus (New York City Board of Health; Dryvax™, Wyeth Laboratories, Marietta, PA). Ongoing evaluation of health outcomes among Armed Forces personnel indicates individuals vaccinated for smallpox are at higher risk for myopericarditis than those not vaccinated. A program for initial and long-term follow-up of individuals diagnosed with smallpox vaccine associated myopericarditis has been established. For active duty, National Guard and Reserve Component personnel, including those previously or about to be demobilized, separated, or discharged, it is important that appropriate follow-up take place.

All separating and demobilizing personnel with a clinically verified diagnosis of post-smallpox vaccine myopericarditis shall be enrolled in the central registry maintained by the VHC Network. This clinically verified diagnosis will be appropriately annotated in the servicemembers medical record, and IAW Service policy, the appropriate Line of Duty determinations will be established. Each Service will coordinate with the Military Medical Support Office (1-888-MHS-MMSO), as needed, to provide appropriate civilian medical follow-up and payment arrangements for Reserve Component personnel.

William Winkenwerder, Jr., M.D.

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: David Tornberg, DASD Clinical and Program Policy

SUBJECT: Smallpox Vaccine Adverse Event Follow-up of Guard and Reserve Component Personnel

- The ASD(HA) should sign the memo at TAB A.
- Smallpox vaccine has been associated with new onset myopericarditis. A program for initial and long-term follow-up of individuals diagnosed with smallpox vaccine associated myopericarditis has been established (TAB B). The longer-term morbidity among these individuals will significantly impact future decisions on smallpox vaccination. As Guard and Reserve component personnel are demobilized, it is important that appropriate follow-up continue to take place.
- The memorandum at TAB A directs Line of Duty (LOD) statement for vaccinated personnel with cardiac complications. Those individuals requiring medical treatment/evaluation should be retained on Active Duty pending resolution of the medical condition or completion of the physical disability evaluation. The memo was coordinated with Service M&RA and other offices (TAB C) with no objections noted.

RECOMMENDATION: That the ASD(HA) sign memorandum to M&RA's at TAB A.

COORDINATION: TAB D

Attachments:
As stated

Prepared by: LtCol [redacted] C&PP, [redacted] PCDOCS# 50272

TAB B

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

JUN -9 2003

MEMORANDUM FOR DEPUTY SURGEON GENERAL OF THE ARMY
DEPUTY SURGEON GENERAL OF THE NAVY
DEPUTY SURGEON GENERAL OF THE AIR FORCE

SUBJECT: Establishment of Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis

REFERENCES:

1. Deputy Secretary of Defense Memorandum, "Smallpox Vaccination Program," September 30, 2002
2. Under Secretary of Defense for Personnel and Readiness Memorandum, "Policy on Administrative Issues Related to Smallpox Vaccination Program (SVP)," December 13, 2002
3. Assistant Secretary of Defense for Health Affairs Memorandum, "Clinical Policy for the DoD Smallpox Vaccination Program (SVP)," November 26, 2002

Myopericarditis has historically been associated with vaccination for smallpox (vaccinia virus). Until recently, it has been a rare or unrecognized event after vaccination with the currently utilized strain of vaccinia virus (New York City Board of Health; Dryvax®, Wyeth Laboratories, Marietta, PA). Ongoing evaluation of health outcomes among Armed Forces personnel indicates individuals vaccinated for smallpox are at higher risk for myopericarditis than those not vaccinated. Ongoing review of cases diagnosed to date indicate a need to standardize evaluation and clinical management to decrease variation and provide ready access to clinical consultative services, assure access to care for longer-term follow-up for individuals separating from active duty, reserve component and National Guard personnel, and a need to document outcomes for future smallpox vaccine program management.

This memorandum provides a uniform approach for evaluation and establishes a program for consultation and long-term follow-up of individuals diagnosed with smallpox vaccine associated myopericarditis. A tri-service team supporting the DoD Vaccine Healthcare Center (VHC) Network developed the attached guidelines for clinicians. Forward deployed medical support units should be aware of and use the guidelines for the diagnosis and treatment of myopericarditis associated with smallpox vaccination. The guidelines will be modified in an iterative process as new information and clinical experience evolve, and will be available at www.vaccines.mil. To support clinicians seeking multi-disciplinary consultation, the Military Vaccine (MILVAX) Agency established a 24/7 toll-free bridge number for short-notice teleconferencing. Clinicians wishing to consult via this teleconference bridge with VHC staff and/or military cardiologists regarding optimal care should call the DoD Vaccine Clinical Call

Center at (866) 210-6469. Additional consultative support is available via e-mail at ASkVHC@amedd.army.mil.

All DoD beneficiaries, including Reserve component personnel who received their smallpox vaccine while in a duty status, with a clinically verified diagnosis of post-smallpox vaccine myopericarditis will be enrolled in the central registry maintained by the VHC Network and be followed using the attached clinical guidelines for a minimum of 12 months from the date of initial diagnosis. The Vaccine Adverse Event Reporting System (VAERS) should be used according to service policy. Patient informed consent is not required as part of enrollment. Enrollment in this registry will facilitate long-term clinical follow-up, delivery of appropriate clinical care, and a greater understanding of potential sequelae of this clinical manifestation. Upon enrollment VHC staff should help ensure appropriate 6 and 12-month follow-up in coordination with the patient's case manager.

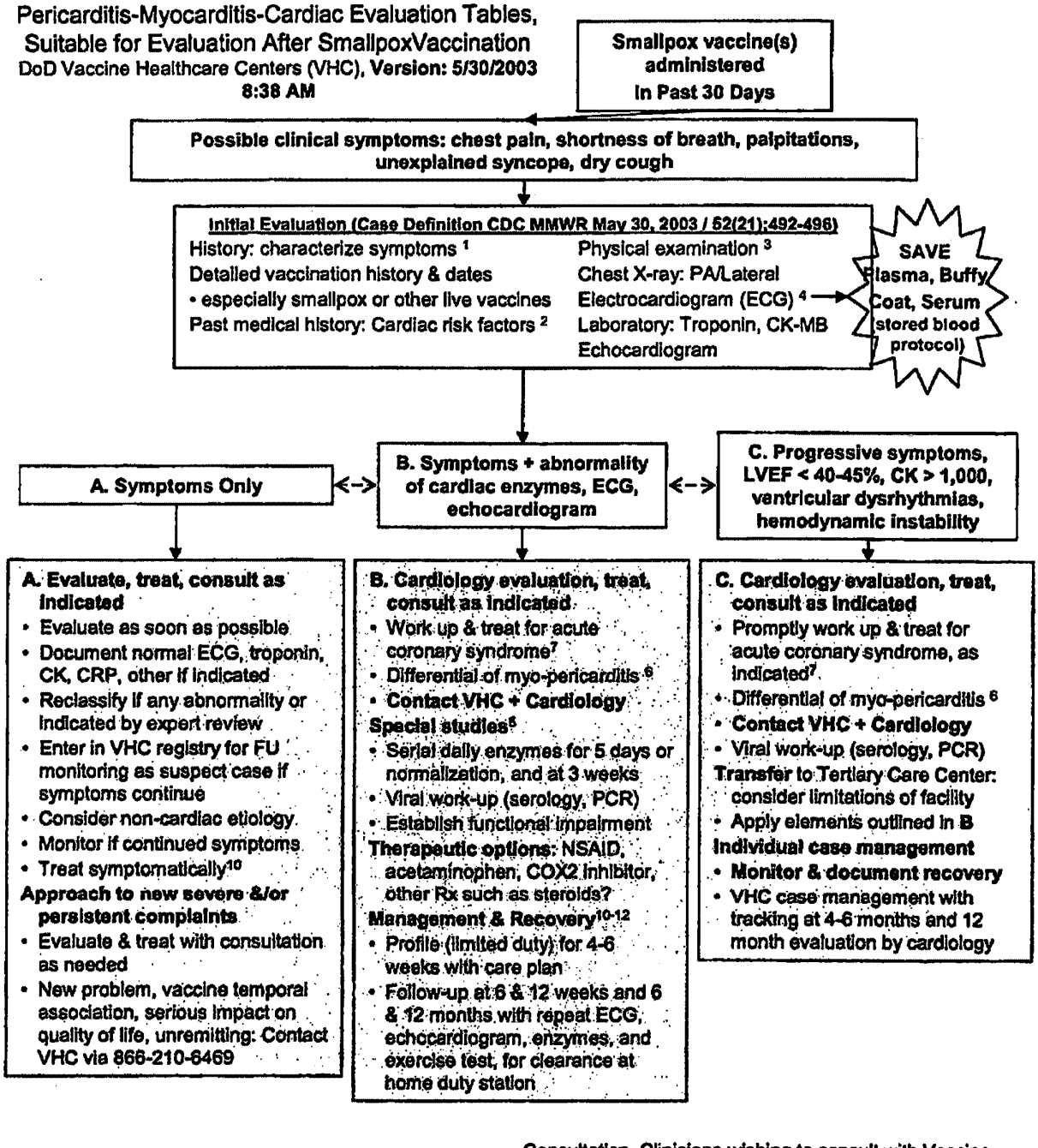
Those individuals requiring medical treatment/evaluation should be retained on Active Duty pending resolution of the medical condition or completion of the disability evaluation. Each Service will coordinate with the Military Medical Support Office (1-888-MHS-MMSO), as needed, to provide appropriate civilian medical follow-up and payment arrangements for Reserve Component personnel.

David N. Tornberg, MD, MPH
Deputy Assistant Secretary of Defense
Clinical and Program Policy

Attachment:
As stated

Pericarditis-Myocarditis-Cardiac Evaluation Tables, Suitable for Evaluation After SmallpoxVaccination

DoD Vaccine Healthcare Centers (VHC), Version: 5/30/2003 8:38 AM



A-C Refer to VHC Network for second level review (CISA/CDC/VHC): Echocardiograms, ECGs, cardiac isoenzyme results, copy of records and patient and provider contact information. **Key VHC Consultant Sites:** Brooke & Walter Reed AMC

Consultation. Clinicians wishing to consult with Vaccine Healthcare Center and/or military cardiologists regarding optimal care should call the DoD Vaccine Clinical Call Center at 866-210-6469, to request a clinical cardiovascular consult. **NOTE:** Footnotes and additional information described on accompanying sheets.

Recommended Pericarditis-Myocarditis-Cardiac Evaluation Guidelines Suitable for Evaluation Post-Smallpox Vaccination

DoD Vaccine Healthcare Centers (VHC), 30 May 2003

Footnote #	Topic	Documentation Categories	Documentation Details, Comments
1	Chest pain type	Category of patient's chest pain type if present (choose one): I. Atypical chest pain: Pain, pressure, or discomfort in the chest, neck, or arms not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin II. Stable chest pain: Chest pain without a change in frequency or pattern for the 2 weeks before this procedure. Chest pain is controlled by rest and/or sublingual/oral/transcutaneous medications. III. Unstable chest pain: Chest pain that occurred at rest and was prolonged, usually lasting more than 20 minutes. Recent acceleration of chest pain reflected by an increase in severity	
	Number of episodes of chest pain in last 72 hours	Number of distinct episodes of chest pain that occurred in the last 72 hours before evaluation	
	Secondary cause of chest pain (yes/no)	Note whether the chest pain was precipitated by a secondary factor such as known atherosclerotic coronary artery disease, fever, anemia, hypoxemia, tachycardia, thyrotoxicosis, or severe valvular disease	
	Reproducibility of symptoms	Note whether the chest pain is reproducible by either deep respiration (pleuritic), positional changes or pressure sensitive	
	Heart failure	Patient with complaint of dyspnea on exertion, resting shortness of breath, paroxysmal nocturnal dyspnea, orthopnea, edema, weight gain	
	Dysrhythmia	Patient with complaint of palpitations, rapid or slow heart rate. Documentation of concominant symptoms of syncope (duration), dizziness or light headedness associated with symptoms	
2	Prior angina	History of angina before the current admission. "Angina" refers to evidence or knowledge of symptoms before this acute event described as chest pain or pressure, jaw pain, arm pain, or other equivalent discomfort suggestive of cardiac ischemia. Indicate if angina existed more than 2 weeks before admission and/or within 2 weeks before admission.	
	Previous myocardial infarction (MI)	The patient has had at least 1 documented previous MI before admission.	
	Prior congestive heart failure (CHF)	History of CHF. "CHF" refers to evidence or knowledge of symptoms before this acute event described as dyspnea, fluid retention, or low cardiac output secondary to cardiac dysfunction, or the description of rales, jugular venous distension, or pulmonary edema before the current admission.	
	Previous percutaneous coronary intervention (PCI)	Previous PCI of any type (balloon angioplasty, atherectomy, stent, or other) done before the current admission. Date should be noted.	
	Previous coronary artery bypass graft (CABG)	Previous CABG done before the current admission. Date should be noted.	
	Prior catheterization with stenosis greater than or equal to 50%	Documented coronary artery disease (CAD) at coronary angiography at any time before the current admission, with at least a 50% stenosis in a major coronary artery. If the patient had a cardiac catheterization before the index event that demonstrated a stenosis of 90% and that was successfully stented to a 0% residual, this should be coded as "yes," because a stenosis of greater than or equal to 50% was documented.	
	History of stroke	Documented history of stroke or cerebrovascular accident (CVA). Typically, a patient has had a history of stroke if there was loss of neurological function caused by an ischemic event with residual symptoms at least 24 hours after onset. The year of the most recent stroke before the current admission should be noted.	
	History of transient ischemic attack (TIA)	A focal neurological deficit (usually corresponding to the territory of a single vessel) that resolves spontaneously without evidence of residual symptoms at 24 hours	
	Peripheral arterial disease	Peripheral arterial disease can include the following: 1. Claudication, either with exertion or at rest 2. Amputation for arterial vascular insufficiency 3. Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities 4. Documented aortic aneurysm 5. Positive noninvasive test (e.g., ankle brachial index less than 0.8)	

	Diabetes	History of diabetes, regardless of duration of disease, need for antidiabetic agents, or a fasting blood sugar greater than 7 mmol/l or 126 mg/dl. If yes, the type of diabetic control should be noted (check all that apply): 1. None 2. Diet: Diet treatment 3. Oral: Oral agent treatment 4. Insulin: Insulin treatment (includes any combination of insulin)
	Hypertension	Hypertension as documented by: 1. History of hypertension diagnosed and treated with medication, diet, and/or exercise 2. Blood pressure greater than 140 mmHg systolic or 90 mmHg diastolic on at least 2 occasions 3. Current use of antihypertensive pharmacological therapy
	Smoking	History confirming cigarette smoking in the past. Choose from the following categories: 1. Current: Smoking cigarettes within 1 month of this admission 2. Recent: Stopped smoking cigarettes between 1 month and 1 year before this admission 3. Former: Stopped smoking cigarettes greater than 1 year before this admission 4. Never: Never smoked cigarettes
	Dyslipidemia	History of dyslipidemia diagnosed and/or treated by a physician. National Cholesterol Education Program criteria include documentation of the following: 1. Total cholesterol greater than 200 mg/dl (5.18 mmol/l); or 2. Low-density lipoprotein (LDL) greater than or equal to 130 mg/dl (3.37 mmol/l); or 3. High-density lipoprotein (HDL) less than 40 mg/dl (1.04 mmol/l). Treatment is also initiated if LDL is greater than 100 mg/dl (2.59 mmol/l) in patients with known coronary artery disease, and this *would* qualify as hypercholesterolemia.
	Family history of CAD	Any direct blood relatives (parents, siblings, children) who have had any of the following at age less than 55 years: 1. Angina 2. MI 3. Sudden cardiac death without obvious cause
	Lung disease	Documented history of chronic lung disease (i.e., chronic obstructive pulmonary disease) or currently being treated with pharmacological therapy (e.g., inhalers, theophylline, aminophylline, or steroids) and/or has a forced expiratory volume in 1 second (FEV1) less than 75%, room air pO2 less than 60%, or room air pCO2 greater than 50%. Acute lung injury to include pulmonary embolism/deep vein thrombophlebitis.
	Gastrointestinal disease	Documented history of either gastroesophageal reflux disease, esophagitis, peptic ulcer disease, or currently being treated with pharmacologic therapy (e.g. H_2-antagonists (cimtedine, ranitidine, etc.), or proton pump inhibitors (omeprazole, lansoprazole, etc.)). History of pancreatitis or cholelithiasis or other gallbladder disease.
	Prior vaccination history and adverse events	Note made of all vaccinations received within 30 days of presentation, to include location of immunization. Note made of prior adverse reactions with vaccinations to include, but not limited to, arthralgias, myalgias, headache, shortness of breath, chest pain, febrile illness
3	Gender	Patient's gender: male or female
	Date of birth	Day, month, and year of the patient's birth
	Race	Patient's race: 1. White 2. Black 3. Hispanic 4. Asian 5. Native American 6. Other race not listed (Note: These categories could be used in a "check all that apply" format to identify mixed races.)
	Heart rate	Heart rate (beats per minute) should be the recording that was done closest to the time of presentation to the healthcare facility
	Systolic and diastolic blood pressure (at time of presentation	Supine systolic and diastolic blood pressure (mmHg) should be the recording that was done closest to the time of presentation to the healthcare facility and on

Recommended Pericarditis-Myocarditis-Cardiac Evaluation Guidelines Suitable for Evaluation Post-Smallpox Vaccination

DoD Vaccine Healthcare Centers (VHC), 30 May 2003

	and on discharge)	discharge
	Respiratory rate	Respiratory rate (breaths per minute)
	Temperature	Temperature (in Fahrenheit or Celsius) with indication as to method taken, either aural, oral, rectal, or non-invasive (skin probe). Should be the recording that was done closest to the time of presentation to the healthcare facility
	Height	Patient's height in centimeters or inches
	Weight	Patient's weight in kilograms or pounds
	Vaccination site	Vaccination site healing?
	Cardiac exam	Heart rate regular/irregular, absence/presence of S4, S3 Absence/presence of murmur or rub Point of maximal impulse (PMI, apex) lateral
	Jugular venous pressure	Normal/elevated
	Lung exam	Rales, wheezes, etc. None (absence of rales over the lung fields) Mild CHF (rales over 50% or less of the lung fields). Evidence of new pulmonary vascular congestion on chest radiograph also meets the definition. Severe CHF (rales over more than 50% of the lung fields). Evidence of pulmonary edema on chest radiograph would also meet this definition.
	Extremities	Edema on peripheral extremities, with notation as to evidence of sustained depression (pitting), and amount of depression (in millimeters, or 1-4+ scale)
	Lymphatics	Adenopathy with documentation of location (ancillary, clavicular, submental, cervical, inguinal)
4	First 12-lead ECG: date and time	Note date and time the first 12-lead ECG was performed for acute episode (whether in a prehospital setting, emergency department, or inpatient unit).
	Location of ECG changes	The location of each type of ECG change listed below can be broken into 4 categories: 1. Inferior leads: II, III, aVF 2. Anterior leads: V1 to V4 3. Lateral leads: I, aVL, V5 to V6 4. Diffuse leads: use if similar type of ECG changes identified in ≥9 of 12 leads.
	Type of ECG changes	1. ST-segment elevation indicates greater than or equal to 1 mm (0.1 mV) elevation in 2 or more contiguous leads 2. ST-segment depression of at least 0.5 mm (0.05 mV) in 2 or more contiguous leads (includes reciprocal changes) 3. T-wave inversion of at least 1 mm (0.1 mV) including inverted T waves that are not indicative of acute MI 4. Q waves refer to the presence of Q waves that are greater than or equal to 0.03 seconds in width and greater than or equal to 1 mm (0.1 mV) in depth in at least 2 contiguous leads
	Bundle-branch block (BBB) and type	The presence of left or right BBB should be noted, as well as whether it is new, old, or of uncertain timing
	Rhythm	The categories of rhythm are as follows: 1. Sinus rhythm 2. Atrial fibrillation (or flutter) 3. Paced 4. Other rhythm (e.g., ventricular tachycardia, supraventricular tachycardia)
	Conduction abnormality	1.Conduction abnormalities including: Ventricular tachycardia 2. Supraventricular tachycardia 3. Sinus arrhythmia 4. Premature beats to include premature ventricular complexes (PVC), premature supraventricular/atrial complexes (PACs).

Recommended Pericarditis-Myocarditis-Cardiac Evaluation Guidelines
Suitable for Evaluation Post-Smallpox Vaccination
DoD Vaccine Healthcare Centers (VHC), 30 May 2003

5			
	Complete blood count	The presentation CBC, to include differential, with emphasis on eosinophil and lymphocyte count should be noted. The upper limit of normal of WBC, Hgb, Plt, and differential as determined by individual hospital laboratory standards should be reported.	
	Cardiac enzymes		
	All values	All CK, CK-MB, and troponin values during the evaluation should be noted; include the units, date, and time. The upper limit of normal of CK-MB as defined by individual hospital laboratory standards should be noted. For troponin values, indicate which type: T or I.	
	B-type natriuretic peptide		
	All values	All BNP values during the hospitalization should be noted; include units, date, and time	
	Inflammatory markers		
	All values	All erythrocyte sedimentation rate and C-reactive protein values during the evaluation should be noted; include units, date, and time. Report the upper limit of normal as defined by individual hospital laboratory standards.	
	Immune complex screening		
	All values	All C3, C4, CH50, Raji cell, C1q assay values during the evaluation should be noted; include units, date, and time. Report the upper limit of normal as defined by individual hospital laboratory standards.	
	Cultures: Viral		
	All values	All viral cultures (nasal wash, urine, feces) for adenovirus, influenza viruses or enteroviruses should be noted to include date and time. Results of cerebrospinal fluid viral cultures including shell vial culture that looks specifically for enteroviruses, herpes simplex viruses, and cytomegalovirus should be noted to include date and time.	
	Serologies: Viral		
	All values	All enterovirus, influenza, coxsackie B, Lyme, hepatitis B IgM and core IgG values and titers during the evaluation should be noted; include units, date, and time to differentiate between acute and convalescent sera.	
	Collagen vascular screening		
	All values	All ANA, Anti-DS DNA, ENA, etc. values during the evaluation should be noted; include units, date, and time. Report the patterns associated with positive assays.	
	Other labs		
	Total serum cholesterol level	The first total serum cholesterol level and type of units should be noted	
	LDL	First serum low density lipoprotein (LDL) and units (either calculated or direct, if measured)	
	HDL	First serum high density lipoprotein (HDL) level and units	
		First serum C-reactive protein level and units	
	Serum creatinine	First creatinine level and units	
	Hemoglobin A1c	Documented laboratory value and units for patient's hemoglobin A1c	
6	Pericarditis, myocarditis Case definition items (Case Definition CDC MMWR May 30, 2003 / 52(21);492-496)	Elevated cardiac enzymes	↑ Troponin, CK-MB, and/or CK
		Electrocardiogram (ECG) abnormalities	ECG: No evolution to Q waves
		Physical findings	Rub, S3
		Chest x-ray	Heart failure signs
		Echocardiogram abnormalities	Pericardial effusion, ↓ left-ventricular (LV) function
		±Magnetic resonance imaging (MRI) with gadolinium ±^{111}In-Cardiac scanning	Pericardial versus myocardial uptake

Recommended Pericarditis-Myocarditis-Cardiac Evaluation Guidelines Suitable for Evaluation Post-Smallpox Vaccination

DoD Vaccine Healthcare Centers (VHC), 30 May 2003

		±Endomyocardial biopsy (exclude active vaccinia by PCR before recommending steroids) ±Viral diagnostics	Characteristic histology
7	Stress test	Indicate whether an exercise tolerance or pharmacological stress test was performed during the hospital stay. Date should be noted. Indicate if the test involved ECG alone, or either radionuclide, imaging or echocardiogram.	
	Ischemia result (positive, negative, equivocal)	Positive: On an exercise tolerance test, the patient developed either: a. Both ischemic discomfort and ST shift greater than or equal to 1 mm (0.1 mV) (horizontal or downsloping) or b. New ST shift greater than or equal to 2 mm (0.2 mV) (horizontal or downsloping) believed to represent ischemia even in the absence of ischemic discomfort If the patient had an equivalent type of exercise test (e.g., exercise thallium or MIBI test, stress echocardiography, or dipyridamole, thallium, or adenosine radioisotope scan) that showed definite evidence of ischemia (e.g., an area of clear reversible ischemia), this should be considered a positive test. 2. Negative: No evidence of ischemia (i.e., no typical angina pain and no ST shifts). 3. Equivocal: Either: a. Typical ischemic pain but no ST shift greater than or equal to 1 mm (0.1 mV) (horizontal or downsloping) or b. ST shift of 1 mm (0.1 mV) (horizontal or downsloping) but no ischemic discomfort c Imaging testing Note presence or absence of a fixed defect indicating an old MI	
	Ejection fraction (EF)	The first EF obtained during the hospital stay. It is the percent of blood emptied from the ventricle at the end of contraction and can be obtained, in preferred order, from a left ventriculogram, radionuclide ventriculography, or echocardiogram. If only a range is estimated for EF, the midpoint of the range should be the value noted. Note type of test used for EF: contrast ventriculography, radionuclide ventriculography or echocardiography. Note also whether it was estimated or calculated.	
	Cardiac catheterization	Diagnostic cardiac catheterization/angiography performed during the hospital stay. Date should be noted. Note percentage occlusion, from 0 to 100%, associated with the identified vessel systems. In instances where multiple lesions are present, enter the highest percentage stenosis noted. The systems of interest are as follows and should include major branch vessels of greater than 2 mm diameter: LAD or any major branch vessel, LCx or any major branch vessel, RCA or any major branch vessel, left main, bypass grafts	
8	Other special studies	Auto-antibodies for myocardium Special studies on biopsy	To be developed
9	Normal tests but persistent symptoms	If symptoms persist > 3 months, consider further evaluation with specialty referrals, VHC referral.	To be developed
10	Therapeutic options • Mild to moderate	Aspirin or non-steroidal anti-inflammatory therapy	To be developed
11	Therapeutic options • Symptoms, normal LV function, evidence of inflammation	Corticosteroids?	To be developed
12	Therapeutic options • Symptoms, abnormal LV function (e.g., LV ejection fraction, LVEF) • Evidence of inflammation? • Progressive disease	Corticosteroids? Vaccinia Immune Globulin?	To be developed

Version: 5/30/2003 8:44 AM

TAB C

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D C 20301-1200

HEALTH AFFAIRS

JUL 22 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT. Coordination of Memorandum to Establish Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis

The Department of Defense's ongoing evaluation of health outcomes among Armed Forces personnel vaccinated for smallpox indicates those who received the vaccine are at higher risk for myopericarditis than those not vaccinated The proposed memo (attachment one) describes an established program (attachment 2) for initial and long-term follow-up of individuals diagnosed with smallpox vaccine associated myopericarditis As applied to personnel (including Reserve Component personnel) separating or who have separated from active duty, it directs appropriate line of duty determinations and medical record documentation in accordance with Service policy and procedure to assure effective long-term follow-up.

Please review the proposed memo and provide comments to my point of contact, Lt Col [redacted] ex [redacted] by close of business August 8, 2003

William Winkenwerder, Jr , MD

Attachments
As stated

Coordination of Memorandum to Establish of Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis

COORDINATION

Prog Dir CPI	CAPT [redacted]	Concurred 7/19/03
DASD (FHP&R)	Ms. Ellen Embrey	Concurred 6/24/03
ASD, RA	Mr (b)(6) [redacted]	Concurred ~~7/14/03~~ 7/22/03
CoS, HA	Ms [redacted]	(b)(6) [redacted]
PDASD(HA)	Mr [redacted]	_____

Coordination of Memorandum to Establish of Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis

COORDINATION

Prog.Dir CPI	[redacted]	
DASD (C&PP)	Dr. Tornberg	
DASD (FHP&R)	Ms. Ellen Embrey	
CoS, HA	(b)(6)	
PDASD(HA)		

Coordination of Memorandum to Establish of Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis

COORDINATION

Prog Dir CPI	(b)(6)	(b)(6)
DASD (PHP&R)	**Ms. Ellen Embrey**	*see below EFE 6/24
CoS, HA	(b)(6)	_____
PDASD(HA)		_____

* Looks okay to me but highly recommend you coordinate package with ASD/RA before sending memo's to M&RA's.
— Ellen 6/24

Coordination of Memorandum to Establish of Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis

COORDINATION

Prog Dir CPI	(b)(6)	
DASD (FHP&R)	Ms. Ellen Embrey	
ASD, RA	Mr. Thomas Hall	T H signed 7/14/03
CoS, HA	(b)(6)	
PDASD(HA)		

FAX TRANSMITTAL

(b)(6)		Prgm CAPT	(b)(6)
			(b)(6)
HA			
(b)(6)		Fax #	

DEPARTMENT OF THE AIR FORCE
WASHINGTON DC

Office Of The Assistant Secretary

04 NOV 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM Assistant Secretary of the Air Force (Manpower and Reserve Affairs)

SUBJECT Coordination of Memorandum to Establish Case Management Guidelines for Smallpox Vaccine Associated Myopericarditis (Your Memo, 22 Jul 03)

Thank you for the opportunity to review the draft memorandum to establish case management guidelines for smallpox vaccine associated myopericarditis We concur with the draft memo with no comments

AF healthcare providers have received instructions for the clinical management of myopericarditis associated with smallpox vaccine, in accordance with guidance from the Deputy Assistant Secretary of Defense (Clinical and Program Policy) We are prepared to evaluate and manage vaccinia-associated myopericarditis cases and will ensure that members are enrolled in the central DoD registry for long-term follow-up

If you have questions, please contact Major (b)(6) AFMSA/SGPP, 110 Luke Avenue, Room 405, Bolling AFB, DC 20032-7050, (b)(6) DSN (b)(6) email (b)(6) My point of contact in the Office of the Deputy Assistant Secretary (Force Management and Personnel) is Ms Carol J Thompson, [redacted]

MICHAEL L DOMINGUEZ
Assistant Secretary
(Manpower and Reserve Affairs)

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

REPLY TO
ATTENTION OF

DASG-ZB

06 JUN 2003

MEMORANDUM FOR DEPUTY ASSISTANT SECRETARY OF DEFENSE (CLINICAL AND PROGRAM POLICY)

SUBJECT: Smallpox Vaccine Adverse Event Follow-Up

1. This memorandum responds to your request for coordination of policy of 30 May 2003, subject as above.

2. On 29 March 2003, the Department of the Army announced to units around the world that people with serious heart disease would be deferred from pre-outbreak smallpox vaccination or who have three or more cardiac risk factors, similar to steps taken by the Centers for Disease Control and Prevention (CDC). At present, we are deferring such people. In addition, DoD worked with the CDC and other experts to refine the cardiac-screening process.

3. Your memorandum and algorithms establish a uniform protocol for evaluation and program for consultation and long-term follow-up of individuals diagnosed with smallpox vaccine associated myopericarditis. A tri-service team supporting the DoD Vaccine Healthcare Center Network developed the attached guidelines for clinicians.

4. The Office of The Surgeon General concurs with the memorandum and clinical guidelines as written.

FOR THE SURGEON GENERAL:

Atch

KENNETH L. FARMER, JR., M.D.
Major General
Deputy Surgeon General

Smallpox Vaccine Adverse Event Follow-up of Guard and Reserve Component Personnel

COORDINATION

DASD (FHP&R)	**Ms. Ellen Embrey**	
CoS, HA	(b)(6)	
PDASD(HA)		

2003023-000024

27

HA/TMA Document Profile

46207

Subject: Anthrax and Smallpox Vaccines to DoD Personnel and Family Members Overseas

Author:	Armitage, Richard L.	**Congressional Name:**	
Date of Document:	2/21/2003	**Input By:**	[redacted]
OSD # :	U02290-03	**Profiler's Directorate:**	Admin, HA
PR # :	0105173	**Response Signed By:**	
Organization:	Department of State	**Dt Response Signed:**	
Department:		**Doc Type:**	LETTER
Assigned To:	DHS	**Application:**	DOCSIMAGE
Prepared For:	ASD	**Previous Documents:**	
Suspense Date:	3/6/2003	**Related Documents:**	
Coord Office(s):		**Notes:**	

Beneficiary Info

Beneficiary Name:	
Address 1:	
Apartment #	
Phone #	
Email Address:	
City:	
State:	**Zip**

History

Created:	2/24/2003	HA PCDOCS Adr
Edited:	2/24/2003	HA PCDOCS Adr
Status:	Available	

Retention Schedule

Type: Archive

Retention Days: 365

☐ **From External Source?**

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☐ **Enable Content Searching**

ACTION MEMO

May 23, 2003, 7:15 AM

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL AND READINESS)

FROM: William Winkenwerder Jr., MD, Assistant Secretary of Defense (Health Affairs)

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Offered Anthrax and/or Smallpox Vaccines on a Voluntary Basis Because of Location in a High Threat Area.

- Attached is a supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines on a voluntary basis because of location in a high threat area (HTA).

- The policy provides a matrix graphically explaining those categories of personnel, the general locations, and circumstances in which a person may receive anthrax and/or smallpox vaccinations in accordance with existing OSD policies.

- The Services agree the intent of policy; however, they recommend the immediate declassification of Dr. Chu's memo listing the countries considered a DoD high-threat area and to include these countries in the policy document. These recommendations were not accepted due to the dynamic nature of the DoD HTA list, which would require a continual updating of policy.

RECOMMENDATION: Sign policy memorandum at TAB A

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR [redacted] DHSD, [redacted] PCDOCS#46207

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
UNDER SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
COMMANDANT OF THE COAST GUARD
DIRECTOR, JOINT STAFF

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Offered the Anthrax and/or Smallpox Vaccines on a Voluntary Basis Because of Location in a High Threat Area.

The February 14, 2003, Deputy Secretary of Defense memorandum, Subject: Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions in High-Threat Areas, and the March 13, 2003, Assistant Secretary of Defense (Health Affairs) memorandum, Subject: Clarification of Service Responsibilities in Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions or Residing in Higher-Threat Areas, directed the Military Departments to provide anthrax and smallpox vaccinations on a voluntary basis to categories of persons in certain overseas high threat areas. This memorandum provides supplementary administrative guidance for individuals offered the anthrax and smallpox vaccines on a voluntary basis because of location in a high threat area.

In an effort to support the DoS, their measures to protect personnel, and DoD personnel supporting the DoS mission, policies were issued to delineate these efforts. However, other categories of individuals, locations, and circumstances were identified as not being specifically addressed. Table 1 (attached) is a matrix explaining those categories of personnel and the locations and circumstances in which a person may receive anthrax and /or smallpox vaccinations.

The Services are directed to meet all the same educational, clinical, and administrative requirements to administer vaccinations for these categories of personnel as directed in previous administrative and clinical policies for both the DoD Anthrax Vaccine Immunization Program and the Smallpox Vaccination Program.

It is essential that individuals receiving the Anthrax and/or Smallpox Vaccines on a voluntary basis complete an acknowledgement form prior to receiving these immunizations. These forms can be found on DoD's MILVAX website: www.vaccines.army.mil. The signed form must be entered into the individual's medical record.

The Services are directed to document all immunizations, preferably in their service's automated immunization tracking system, as each system's capability allows. At a minimum, immunizations should be documented in the individual health record and the International Certificates of Vaccination, PHS-731.

When practicable, adverse events in any individual receiving immunizations on a voluntary basis should be evaluated at the closest Medical Treatment Facility (MTF). Vaccine Adverse Events Reporting System (VAERS) forms should be submitted in accordance with existing Service reporting procedures. VAERS forms are available at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in the implementation of the anthrax and smallpox immunization programs. Questions regarding this memorandum should be directed to the Director, Military Vaccine Agency at (703) 681-5101.

David S. C. Chu

Attachment:
As stated

ANTHRAX AND /OR SMALLPOX VACCINATIONS MATRIX

Table 1

Personnel Category	Located in DoD HTA	Located in a Non-DoD HTA; but in DoS HTA; assigned to DoS mission	Located in a Non-DoD HTA; but in DoS HTA; not assigned to DoS mission	Conditions:
	Vaccination is:	**Vaccination is:**	**Vaccination is:**	
Military	Mandatory	Permitted, Voluntary	Not Permitted	
Adult FM of Military member	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Emergency Essential DoD Civilian (E-E)*	Mandatory	Permitted, Voluntary	Not Permitted	Civilian Personnel Procedures Apply
Non-E-E	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	Civilian Personnel Procedures Apply
Adult FM of DoD Civilian (E-E and Non-E-E)	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Mission Essential Contractor (MEC)**	Mandatory	Permitted, Voluntary	Not Permitted	If mandatory, must be stated in contract
Non-MEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Adult FM of Contractor (MEC and Non-MEC)	Not Permitted	Not Permitted	Not Permitted	

* DoD civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1999

** Contractor personnel performing mission essential services as described in DoDI 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," November 6, 1990

SIGNED RESPONSE

ACTION MEMO

April 15, 2003, 2:15 p.m.

FOR: William Winkenwerder Jr., MD, ASD (Health Affairs)

FROM: Ms. Ellen P. Embrey, DASD, Force Health Protection and Readiness
//s//4/14/03

SUBJECT: Request for Coordination on Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

- Attached is a draft supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines under the Department of Defense Voluntary Immunization Program to forward for coordination with the Services, Joint Staff, and appropriate offices (TAB B).

- The policy provides a matrix graphically explaining those categories of personnel, and the locations and circumstances in which they may receive anthrax and/or smallpox vaccinations in accordance with existing Office of the Secretary of Defense policies.

- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: That the ASD (HA) sign the memorandum at TAB A

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR [redacted] DHSD, [redacted] PCDOCS# 48381

ACTION MEMO

FOR: UNDER SECRETARY OF DEFENSE (PERSONNEL & READINESS)

FROM: William Winkenwerder Jr., MD, ASD (Health Affairs)

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

- Attached is a draft supplemental policy memorandum for individuals receiving anthrax and/or smallpox vaccines under the Department of Defense Voluntary Immunization Program to forward for coordination with the Services, Joint Staff, and appropriate offices (TAB A).

- The policy provides a matrix graphically explaining those categories of personnel, and the locations and circumstances in which they may receive anthrax and/or smallpox vaccinations in accordance with existing Office of the Secretary of Defense policies.

- Coordinating offices will be given two weeks from the date of the coordinating letter to respond.

RECOMMENDATION: That the USD(P&R) sign the policy memorandum at TAB A and forward for coordination.

COORDINATION: TAB B

Attachments:
As stated

Prepared by: CDR [redacted] DHSD [redacted], PCDOCS# 48381

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D C 20301-1200

APR 2 2 2003

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
DIRECTOR, JOINT STAFF

SUBJECT. Request for Coordination on Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

Request your coordination not later than two weeks from the date of this memorandum on the attached draft policy memorandum delineating those categories of personnel, locations, and circumstances in which a person may receive anthrax and/or smallpox vaccinations under the Voluntary Immunization Program

My point of contact for this matter is CDR [redacted] who may be reached at (b)(6) [redacted] Coordination may be faxed to [redacted] No response will be taken as concurrence

William Winkenwerder, Jr., MD

Attachments
As stated

cc
J-4 (DHS)
Surgeon General, Army
Surgeon General, Navy
Surgeon General, Air Force
Medical Officer, HQ, US Marine Corps
Director of Health and Safety, US Coast Guard

DRAFT

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETRAY OF THE AIR FORCE (M&RA)
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
GENERAL COUNSEL, DEPARTMENT OF DEFENSE

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program

The February 14, 2003, Deputy Secretary of Defense memorandum, Subject: Vaccinating Department of Defense (DoD) Personnel and Dependents Assigned to Department of State (DoS) Missions in High-Threat Areas, and the March 13, 2003, Assistant Secretary of Defense (Health Affairs) memorandum, Subject: Clarification of Service Responsibilities in Vaccinating Department of Defense Personnel and Dependents Assigned to Department of State Missions or Residing in High-Threat Areas, directed the services to provide anthrax and smallpox vaccinations on a voluntary basis to categories of persons in certain overseas high-threat areas. This memorandum provides supplementary administrative guidance for a Voluntary Immunization Program (VIP) with anthrax and smallpox vaccines.

In an effort to support the DoS measures to protect personnel, and DoD personnel supporting the DoS mission, policies were issued to delineate these efforts. However, other categories of individuals, locations, and circumstances were identified as not being specifically addressed.

Table 1 (attached) is a matrix graphically explaining those categories of personnel and the locations and circumstances in which a person may receive anthrax and/or smallpox vaccinations in accordance with the above Office of the Secretary of Defense (OSD) policies.

The Services are directed to meet all the same educational, clinical, and administrative requirements to administer vaccinations in these categories of personnel as directed in previous OSD administrative and clinical policies for both the DoD Anthrax Vaccine Immunization Program and Smallpox Vaccination Program.

It is essential that individuals receiving the anthrax and/or smallpox vaccines on a voluntary basis be required to complete an acknowledgement form prior to receiving any immunization. These forms can be found on DoD's MILVAX website: www.vaccines.army.mil. The signed form must be entered into the individual's medical record.

The Services are directed to document all immunizations; preferably in their service's automated immunization tracking system, as each system's capability allows. At a minimum, immunizations should be documented in the individual health records, PHS 731.

Adverse events in any individual receiving immunizations under the voluntary immunization program should be evaluated at the closest medical treatment facility. Vaccine Adverse Events Reporting System (VAERS) forms should be submitted in accordance with existing service reporting procedures. VAERS forms are available at www.vaers.org or by calling VAERS at 1-800-822-7967.

This policy is effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in the implementation of the anthrax and smallpox immunization programs.

David S. C. Chu

Attachment:
As stated

Table 1

Personnel Category	Located in DoD HTA	Located in a Non-DoD HTA; but in DoS HTA; assigned to DoS mission	Located in a Non-DoD HTA; but in DoS HTA; not assigned to DoS mission	Conditions:
	Vaccination is:	Vaccination is:	Vaccination is:	
Military	Mandatory	Permitted, Voluntary	Not Permitted	
Adult FM of Military member	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Emergency Essential DoD Civilian (EEC)*	Mandatory	Permitted, Voluntary	Not Permitted	
Non-EEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Adult FM of DoD Civilian (EEC and Non-EEC)	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	
Mission Essential Contractors (MEC)**	Mandatory	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Non-MEC	Permitted, Voluntary	Permitted, Voluntary	Not Permitted	Must be Stated in Contract
Adult FM of Contractor (MEC and Non-MEC)	Not Permitted	Not Permitted	Not Permitted	

* DoD civilian personnel classified as emergency-essential under DoD Directive 1404.10, "Emergency-Essential (E-E) DoD U.S. Citizen Civilian Employees," April 10, 1999.

** Contractor personnel performing mission essential services as described in DoDI 3020.37, "Continuation of Essential DoD Contractor Services During Crisis," November 6, 1990.

Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
Assistant Sec of the Army (M&RA)	____	_____	_____
Assistant Sec of the Navy (M&RA)	____	_____	_____
Assistant Sec of the Air Force (M&RA)	____	_____	_____
OSD (OGC)	____	_____	_____
Dir, Joint Staff	____	_____	_____

Supplemental Administrative Policy Guidance for Individuals Receiving Anthrax and Smallpox Vaccines under a Department of Defense Voluntary Immunization Program.

COORDINATION

DASD, FHP/R	**Ms. Ellen P. Embrey**	**Concurred 4/14/03**
DoD, OGC	(b)(6)	_____
CoS, HA		_____
PDASD, HA		_____

SUBJECT: Supplemental Administrative Policy Guidance for Individuals Offered the Anthrax and/or Smallpox Vaccines on a Voluntary Basis Because of Location in a High Threat Area.

COORDINATIONS

DOD, OGC	(b)(6)	Concur 5/8/03
Army (M&RA)	MG Kendall Farmer	Concur 5/7/03 (not attached - classified)
Navy, (M&RA)	A K Blair	Concur 6/4/03
Air Force, (M&RA)	Mr. Michael Dominquez	Concur 5/8/03 With Comments Attached
DASD, FHP&R	Ms. Ellen P. Embrey	_____
CoS, HA	(b)(6)	_____
PDASD, HA		_____

200363-0000024

(b)(6)
08/21/2003 11:07 AM

To: (b)(6)
cc:

Subject: Supplemental Admin Policy regarding voluntary AVIP/SVP in High Threat Areas

(b)(6)

Per COL (b)(6) the package "Supplemental Admin policy guidance for Individuals offered Anthrax and/or Smallpox Vaccines on a Voluntary Basis because of location in a High Threat Area" can be closed out in the PCDOCs system. Apparently, it is OBE due to discussions of expansion of the AVIP and SVIP programs. Please maintain file in case this needs revisiting at a later date.

Thanks,

(b)(6) CDR, MSC, USN
Anthrax Program Liaison Officer for ASD (Health Affairs) and Deputy Program Director, Population Health,
Deployment Health Support Directorate
(b)(6) Fax (b)(6)

DMMC Control #
2003093-0000012

28

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

April 3, 2003, 10:00 AM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, Force Health Protection & Readiness
(//s// 4-3-03)

SUBJECT: Smallpox Vaccine and Persons with Known Cardiac Disease

- The attached policy memorandum directs the Services to appropriately adjust Service Smallpox Vaccination Programs to include the CDC's Advisory Committee on Immunization Practices (ACIP) recommendations to defer vaccination of persons with known cardiac conditions and/or three or more major cardiac risk factors. The attached CDC/ACIP recommendations delineate the specifics.

- The memorandum has been informally staffed with the preventive medicine officers of all Services, the Joint Staff, and Coast Guard; General Counsel; and the Military Vaccine Agency.

RECOMMENDATION: Sign memo at TAB A.

COORDINATION: TAB B

Prepared by: COL Benedict Diniega/FHP&R/(703) 575-2669/ PCDOCs# 47960, 47861

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Policy for Smallpox Vaccine and Persons with Cardiac Conditions

On March 28, 2003, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) met to review data (summary attached) and consider recommendations for the use of smallpox vaccine in persons with known cardiac condition and/or known cardiac risk factors. After careful deliberation, the committee recommends: 1) add myopericarditis as an expected adverse event of smallpox vaccination, and 2) exempt from vaccination persons with known cardiac condition(s) and persons with three or more known major cardiac risk factors (summary of ACIP recommendations attached). The Services should exempt personnel with the following cardiac conditions: myocardial infarction, angina pectoris, cardiomyopathy, congestive heart failure, stroke, transient ischemic attacks, chest pain or shortness of breath with activity and associated with a heart condition, other coronary artery disease, and other heart conditions under the care of a physician. Persons with any of the listed conditions should be exempted from smallpox vaccination.

The following cardiac risk factors should be identified during pre-immunization processing: current cigarette smoking, hypertension, hypercholesterolemia, diabetes mellitus, and family history of heart disease in 1st degree relative with onset before age 50. Persons with three or more of the above referenced risk factors should be exempted from receiving smallpox vaccine. Along with the ACIP, Health Affairs recommends that recent smallpox vaccine recipients who have a cardiac condition or three or more major cardiac risk factors be evaluated by a health care professional if they develop any symptoms of chest pain, shortness of breath, or other symptoms of heart disease. All people with heart disease or risk factors should receive the routine care recommended for persons with these conditions.

I direct the Services to make appropriate adjustments to their smallpox vaccination programs to incorporate these recommendations. DoD smallpox vaccine education and screening materials will be modified accordingly and posted at www.smallpox.army.mil.

My points of contact are COL Benedict Diniega [redacted], and COL [redacted] (Military Vaccine Agency, [redacted].

William Winkenwerder Jr., MD

Attachment:
As stated

Copy to:
Joint Staff (J-4 (HSSD))
Surgeon General, Army
Surgeon General, Navy
Surgeon General, Air Force
Medical Officer, HQ, U.S. Marine Corps
Director of Health and Safety, U.S. Coast Guard

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

APR 10 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Policy for Smallpox Vaccine and Persons with Cardiac Conditions

On March 28, 2003, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) met to review data (summary attached) and consider recommendations for the use of smallpox vaccine in persons with known cardiac condition and/or known cardiac risk factors. After careful deliberation, the committee recommends: 1) add myopericarditis as an expected adverse event of smallpox vaccination, and 2) exempt from vaccination persons with known cardiac condition(s) and persons with three or more known major cardiac risk factors (summary of ACIP recommendations attached). The Services should exempt personnel with the following cardiac conditions: myocardial infarction, angina pectoris, cardiomyopathy, congestive heart failure, stroke, transient ischemic attacks, chest pain or shortness of breath with activity and associated with a heart condition, other coronary artery disease, and other heart conditions under the care of a physician. Persons with any of the listed conditions should be exempted from smallpox vaccination.

The following cardiac risk factors should be identified during pre-immunization processing: current cigarette smoking, hypertension, hypercholesterolemia, diabetes mellitus, and family history of heart disease in 1st degree relative with onset before age 50. Persons with three or more of the above referenced risk factors should be exempted from receiving smallpox vaccine. Along with the ACIP, Health Affairs recommends that recent smallpox vaccine recipients who have a cardiac condition or three or more major cardiac risk factors be evaluated by a health care professional if they develop any symptoms of chest pain, shortness of breath, or other symptoms of heart disease. All people with heart disease or risk factors should receive the routine care recommended for persons with these conditions.

I direct the Services to make appropriate adjustments to their smallpox vaccination programs to incorporate these recommendations. DoD smallpox vaccine education and screening materials will be modified accordingly and posted at www.smallpox.army.mil.

HA POLICY: 03-002

My points of contact are COL (b)(6), and COL [redacted] (Military Vaccine Agency, (b)(6)).

William Winkenwerder, Jr., MD

Attachments:
As stated

cc:
Joint Staff (J-4 (HSSD))
Surgeon General, Army
Surgeon General, Navy
Surgeon General, Air Force
Medical Officer, HQ, U.S. Marine Corps
Director of Health and Safety, U.S. Coast Guard

Press Release

March 27, 2003
Contact: CDC Press Office
(404) 639-3286

ACIP Summary Statement

The ACIP held an emergency meeting by conference call on Friday, March 28, 2003, to make recommendations to CDC regarding cases of cardiac adverse events that have been reported following smallpox vaccination. A list of participants appears at the bottom of this page.
The specific questions that the Committee was asked to address were:

1. While more information is gathered, are there levels and types of cardiac-related conditions that should be added to the list of reasons for pre-event smallpox vaccine medical deferral?
2. If so, what are the specific pragmatic and feasible methods to screen for these conditions in the vaccine clinic setting?
3. What additional specific operational, policy, or research/investigation advice can the Committee provide to move us forward?
4. Is special follow-up required for persons with cardiovascular risk factors who have been recently vaccinated.

Ten cases of myopericarditis have been reported among several hundred thousand members of the military, and two such cases (one of myocarditis and one of pericarditis) have been reported among civilian vaccinees. Additionally, CDC has received reports of 5 patients with cardiac ischemic events following smallpox vaccination, including 3 patients with myocardial infarctions and two patients with angina. Two of the persons with heart attacks, have died. These cases were reported this week in the *MMWR*.
Options considered by the Committee included:

1. Exclusion of persons with known underlying heart disease, with or without symptoms.
2. In addition to exclusion of persons with known underlying heart disease, exclude those with 3 or more major cardiac risk factors.
3. In addition to exclusion of persons with known underlying heart disease and three or more risk factors, exclude persons 50 years of age and older.

The Committee recommended that CDC exclude persons with known underlying heart disease and persons with 3 or more major cardiac risk factors (option 2). Draft screening questions were presented to the Committee and will be further reviewed with cardiologists and finalized early next week. The Committee approved CDC's proposed research and did not recommend that special medical follow-up was needed for persons with cardiovascular risk factors who had been vaccinated.
However, persons who have received the smallpox vaccine should see a health care provider right away if they develop shortness of breath, chest pain or other symptoms of cardiac disease. Persons who have been diagnosed by a physician as having heart disease and have questions, should contact their heart disease specialist or regular health care provider. All people with heart disease or risk factors should receive the routine care recommended for persons with

these conditions.
The ACIP is an advisory committee of the Centers for Disease Control and Prevention.

Participants on March 28 ACIP Meeting

MODLIN, John F., M.D.
Professor of Pediatrics and Medicine
Dartmouth Medical School

SNIDER, Dixie E., Jr., M.D.
Associate Director for Science
Centers for Disease Control and Prevention
Atlanta, Georgia

BIRKHEAD, Guthrie S., M.D.
Director, Center for Community Health
New York State Department of Health

BONOW, Robert (Cardiologist)
American Heart Association

BROOKS, Dennis A., M.D., M.P.H.
Assistant Professor of Pediatrics
Johns Hopkins School of Medicine
Johnson Medical Center

BRAINWALD, Eugene (retired) (Cardiologist)
Harvard AHA

FOSTER, Valentine (Cardiologist)
Past President AHA

GARDENER, Pierce, M.D.
Fellow of the American College of Physicians Diplomate, ABIM Assoc. Dean of Academic Affairs

GUERRA, Fernando A., M.D.,
Dir. of Health San Antonio Metropolitan Health District

HANSON, I. Celine, M.D.
Bureau Chief
Bureau of Communicable Disease Control
Texas Department of Health

MENSAH, George (Cardiologist)
CDC

LEVIN, Myron J., M.D.
Professor of Pediatrics & Medicine
Chief, Pediatric Infectious Diseases
University of Colorado School of Medicine

NEFF, John M.D. (SP Vac. Safety Working Gp.)
Dir. Center for Children with Special Needs
Div. of General Pediatrics Children's Hospital and Regional Medical Center
Univ. of Washington School of Medicine

NEWCASTLE, Katherine
State Health Dept. AE coordinator

OFFIT, Paul A., M.D.
Chief, Section of Infectious Diseases
The Children's Hospital of Philadelphia

RENNELS, Margaret B., M.D.
Professor, Department of Pediatrics
University of Maryland School of Medicine

SALAMONE, John E.
National Italian American Foundation

SIEGEL, Jane D., M.D. (SP Vaccine Safety Working group (SVSWG))
Professor of Pediatrics
Department of Pediatrics
University of Texas

SMITH, Natalie J., M.D., M.P.H.
Chief, Immunization Branch
Division, Communicable Disease Control
California Department of Health Services

TOMPKINS, Lucy S., M.D., Ph.D.
Professor, Department of Medicine and Microbiology and Immunology
Stanford University Medical Center

Other Who Spoke

GRABENSTEIN, John (DOD)
Deputy Dir. Of Clinical Operations
Smallpox Vaccine Immunization Program
For more information on smallpox, visit http://www.bt.cdc.gov/agent/smallpox/.

###

CDC protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

A SUMMARY OF CARDIAC EVENTS FOLLOWING SMALLPOX VACCINATION

In recent weeks, CDC received several reports of heart-related problems among the 25,645 people who have been vaccinated in the civilian smallpox vaccination program. The seven cases prompting recent precautionary action include three cases of myocardial infarction (heart attack), two cases of angina (cardiac chest pain); and two cases of myopericarditis (inflammation of the heart muscle and/or sac surrounding the heart). In the DoD smallpox vaccination program, fourteen cases of myocarditis and/or pericarditis, and one case of myocardial infarction have occurred among vaccines since the program began on December 13, 2002. In each case, the individual's medical history, including risk factors for heart disease, is being studied.

CDC asked the Smallpox Vaccine Safety Review Board, composed of members from the Armed Forces Epidemiological Board and the Advisory Committee on Immunization Practices to examine reports of heart-related adverse events occurring in connection with the smallpox vaccination programs. This board regularly reviews adverse event data from both the civilian and DoD smallpox vaccination programs. This board met on March 20-21, 2003, to review these cardiac-related adverse events.

SUBJECT: Policy for Smallpox Vaccine and Persons with Cardiac Conditions

COORDINATIONS

COS, FHP&R	COL [redacted]	Concur, 04/03/03
DASD, CP&P	Dr. Tornberg	Concur, 04/02/03
DoD OGC	(b)(6) [redacted]	Concur, 04/02/03

[redacted] on 04/03/2003 08:38:22 AM

To: (b)(6)
cc:

Subject: FW: Smallpox Vaccination in Persons with Cardiac Conditions

Concurrence from Dr. Tomberg.

(b)(6)
COL, MC, US Army
Program Director, Preventive Medicine & Surveillance
Force Health Protection & Readiness (FHP&R)
Office of the Assistant Secretary of Defense for Health Affairs
Skyline 4, Suite 901
5113 Leesburg Pike
Falls Church, VA 22041-3226
Phone: (b)(6)
Fax: (b)(6)
Email: (b)(6)

----Original Message----
From: [redacted] LtCol, OASD(HA)
Sent: Wednesday, April 02, 2003 5:32 PM
To: (b)(6) COL, OASD/HA
Cc: Tomberg, David, DASD/C&PP, OASD(HA)
Subject: RE: Smallpox Vaccination in Persons with Cardiac Conditions

Ben

Dr. Tomberg reviewed the memo and concurs.

Go.

(b)(6)
Lt Col, USAF, BSC
Program Director, Military Public Health
Office of the Assistant Secretary of Defense (Health Affairs)
Clinical and Program Policy
Skyline 5, Suite 601

5111 Leesburg Pike
Falls Church, VA 22041-3206
Phone: DSN (b)(6)
Commercial
Fax: (b)(6)
Email: (b)(6)

-----Original Message-----
From: (b)(6) COL, OASD/HA
Sent: Wednesday, April 02, 2003 4:44 PM
To: (b)(6) LtCol, OASD(HA)
Cc: Tornberg, David, DASD/C&PP, OASD(HA)
Subject: FW: Smallpox Vaccination in Persons with Cardiac Conditions

(b)(6)

Package is attached below.

I've incorporated much of the inputs received from you (b)(6) Didn't get any comments from (b)(6) (b)(6) (b)(6) and COL (b)(6 concur with the rewrite. Please have Dr. Tornberg review and if he concurs, can he send an email of concurrence that we can send forward with the package. (b)(6) (Admin) is entering into PCDOCs and will send for signature tomorrow morning.

Thanks,

(b)(6)

COL, MC, US Army
Program Director, Preventive Medicine & Surveillance
Force Health Protection & Readiness (FHP&R)
Office of the Assistant Secretary of Defense for Health Affairs
Skyline 4, Suite 901
5113 Leesburg Pike
Falls Church, VA 22041-3226
Phone: (b)(6)
Fax: (b)(6)
Email (b)(6)

-----Original Message-----
From: [redacted] COL, OASD/HA
Sent: Wednesday, April 02, 2003 3:48 PM
To: (b)(6)
Subject: Smallpox Vaccination in Persons with Cardiac Conditions

(b)(6)

Attached is policy memo for smallpox vaccination in persons with cardiac conditions.

and will attach as summary. Will also attach summary of ACIP recommendations.

THANKS,

<< File: SMAcardiacE.doc >>

(b)(6)

COL, MC, US Army
Program Director, Preventive Medicine & Surveillance
Force Health Protection & Readiness (FHP&R)
Office of the Assistant Secretary of Defense for Health Affairs
Skyline 4, Suite 901
5113 Leesburg Pike
Falls Church, VA 22041-3226
Phone: (b)(6)
Fax: (b)(6)
Email: (b)(6)

[redacted] on 04/03/2003 09:40:13 AM

To: (b)(6) [redacted]
cc:

Subject: FW: Policy re Cardiac events and smallpox vaccination

Concurrence for General Counsel (b)(6)

(b)(6) [redacted]
COL, MC, US Army
Program Director, Preventive Medicine & Surveillance
Force Health Protection & Readiness (FHP&R)
Office of the Assistant Secretary of Defense for Health Affairs
Skyline 4, Suite 901
5113 Leesburg Pike
Falls Church, VA 22041-3226
Phone: (b)(6)
Fax: (b)(6)
Email: (b)(6)

-----Original Message-----
From: [redacted]
Sent: Wednesday, April 02, 2003 1:20 PM
To: [redacted]
Subject: RE: Policy re Cardiac events and smallpox vaccination

Concur. -(b)(6

-----Original Message-----
From: (b)(6) [redacted]
Sent: Wednesday, April 02, 2003 12:38 PM
To: [redacted]
Subject: Policy re Cardiac events and smallpox vaccination
Importance: High

(b)(6) and (b)(
Attached is "final" draft. Received inputs only from [redacted] (AF), [redacted] (Marines), [redacted] (HA CP&P), (b)(6) I've made changes and am ready to send forward, but would like review from (b)(6) [redacted] (PLEASE!) and [redacted] one last time. I've taken out much of the background

COL [redacted] is reviewing. I'll bring over any changes he makes, but don't think there'll be much.

Please format and edit and put into PCDOCS to forward to Dr. W. for signature. Ms. Embrey hasn't seen yet.

<< File: SMAcardiacE.doc >> << File: r030327.htm >>

(b)(6)

COL, MC, US Army
Program Director, Preventive Medicine & Surveillance
Force Health Protection & Readiness (FHP&R)
Office of the Assistant Secretary of Defense for Health Affairs
Skyline 4, Suite 901
5113 Leesburg Pike
Falls Church, VA 22041-3226
Phone: (b)(6)
Fax: (b)(6)
Email: (b)(6)

TRICARE

TRICARE Management Activity

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

ACTION OFFICE FHPak DATE 4-11-03 PCDOCS # 48373

The attached correspondence is returned for the following reason(s):

- ☐ **Distribution**
- ☐ **Coordination**
- ☐ **Revision**
- ☐ **Correct Signature Block**
- ☐ **Correct Envelope Size**
- ☐ **Correct Letterhead**
- ☐ **Provide Original/Supporting Documents**
- ☐ **Provide SD 391**
- ☑ **Retain for your Files**

(b)(6)

(b)(6)

already made for our files

(b)(6)

Additional Comments:

Come-back copy scanned into PCDocs # 48373

Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

	Sign	Coord		Sign	Coord
4/10/03 ASD, HA TBW	✓		Dir, TMA		
PDASD, HA					
4/2/03 DASD, C&PP		✓	CMO		
4/3/03 DASD, FHP&R		✓	Dir, DHS		
DASD, HB&FP			CFO		
DASD, HPA			COO		
			Dir, TRICARE Operations/PEO		
CIO, MHS			Dir, IMT&R		
4/3/03 OGC, DoD		✓	OGC, TMA		
LA					
CoS, HA		✓	Dir, A&M		
Military Assistant			CoS, TMA		
Dir, PI, HA			Dir, PI, TMA		
Dir, P&S			Dir, Admin		
Other (Specify)			Other (Specify)		

DMD (SKY) Date: **DMD (PNT)** A Date: 4/3/03

Date Received: 4/3/03 **Suspense Date:**

Subject: Smallpox Vaccine and Persons with Known Cardiac Disease

PCDOCS #: 47860, 47861, 47881 **OSD/P&R #:**

AO: COL (b)(6) **Office:** FHP&R **Phone #:** (b)(6)

NOTES: Pkg signed. Distro done by DMD/PNT. Comeback copy to AO. A 4/11/03

DMMC Control #
2003253-0000024

29

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 2 2003

The Honorable John W. Warner
Chairman, Committee on Armed Services
United States Senate
Washington, DC 20510-6050

Dear Mr. Chairman:

I am pleased to forward the report prescribed in section 751 of the National Defense Authorization Act for Fiscal Year 2001. Section 751 requires the Department of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

During the January 1 through December 31, 2002 reporting period, separation and appeal procedures ended for one servicemember, who was subsequently separated from the Armed Forces. During this same period, 72,744 servicemembers received 155,886 doses of licensed anthrax vaccine.

During the January 1 through December 31, 2001 calendar year, two servicemembers were separated as a result of refusing to participate in the AVIP. During the same timeframe, over 28,000 servicemembers participated in the AVIP, receiving over 119, 000 doses of licensed anthrax vaccine.

As of May 25, 2003, over 875,107 servicemembers have participated in the AVIP, receiving over 3,050,671 doses.

Thank you for your support of the Military Health System.

Sincerely,

William Winkenwerder, Jr.

William Winkenwerder, Jr., MD

Enclosure:
As stated

cc:
Senator Carl Levin

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 2 2003

The Honorable Saxby Chambliss
Chairman, Subcommittee on Personnel
Committee on Armed Services
United States Senate
Washington, DC 20510-6050

Dear Mr. Chairman:

I am pleased to forward the report prescribed in section 751 of the National Defense Authorization Act for Fiscal Year 2001. Section 751 requires the Department of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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Sincerely,

William Winkenwerder, Jr., MD

Enclosure:
As stated

cc:
Senator Ben Nelson

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 2 2003

The Honorable Duncan Hunter
Chairman, Committee on Armed Services
House of Representatives
Washington, DC 20515-0552

Dear Mr. Chairman:

I am pleased to forward the report prescribed in section 751 of the National Defense Authorization Act for Fiscal Year 2001. Section 751 requires the Department of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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Sincerely,

William Winkenwerder, Jr., MD

Enclosure:
As stated

cc:
Representative Ike Skelton

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP -2 2003

The Honorable John McHugh
Chairman, Subcommittee on Total Force
House Armed Services Committee
House of Representatives
Washington, DC 20515-6035

Dear Mr. Chairman:

I am pleased to forward the report prescribed in section 751 of the National Defense Authorization Act for Fiscal Year 2001. Section 751 requires the Department of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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Sincerely,

William Winkenwerder, Jr.

William Winkenwerder, Jr., MD

Enclosure:
As stated

cc:
Representative Vic Snyder

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 2 2003

The Honorable Ted Stevens
Chairman, Committee on Appropriations
United States Senate
Washington, DC 20510-6028

Dear Mr. Chairman:

I am pleased to forward the report prescribed in section 751 of the National Defense Authorization Act for Fiscal Year 2001. Section 751 requires the Department of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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Sincerely,

William Winkenwerder, Jr., MD

Enclosure:
As stated

cc:
Senator Robert C. Byrd

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 2 2003

The Honorable Ted Stevens
Chairman, Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510-6028

Dear Mr. Chairman:

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Sincerely,

William Winkenwerder, Jr., MD

Enclosure:
As stated

cc:
Senator Daniel K. Inouye

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 2 2003

The Honorable Jerry Lewis
Chairman, Subcommittee on Defense
Committee on Appropriations
House of Representatives
Washington, DC 20515-6018

Dear Mr. Chairman:

I am pleased to forward the report prescribed in section 751 of the National Defense Authorization Act for Fiscal Year 2001. Section 751 requires the Department of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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Sincerely,

William Winkenwerder, Jr.

William Winkenwerder, Jr., MD

Enclosure:
As stated

cc.
Representative John P. Murtha

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

SEP 2 2003

The Honorable C. W. Bill Young
Chairman, Committee on Appropriations
House of Representatives
Washington, DC 20515-6015

Dear Mr. Chairman:

I am pleased to forward the report prescribed in section 751 of the National Defense Authorization Act for Fiscal Year 2001. Section 751 requires the Department of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program (AVIP).

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Thank you for your support of the Military Health System.

Sincerely,

William Winkenwerder Jr.

William Winkenwerder, Jr., MD

Enclosure:
As stated

cc:
Representative David R. Obey

DEPARTMENT OF DEFENSE
REPORT ON
SEPARATIONS THAT RESULT FROM A REFUSAL TO PARTICIPATE IN THE ANTHRAX VACCINE IMMUNIZATION PROGRAM

January 1 through December 31, 2002 Separations

Service	Separations	Component	Rank	Total
Army	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Navy	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Air Force	1	Active	E-4	1
	0	Guard	n/a	0
	0	Reserve	n/a	0
Marines	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0

Services Total ----------→ 1

(January 1 through December 31, 2002)

DEPARTMENT OF DEFENSE
REPORT ON
SEPARATIONS THAT RESULT FROM A REFUSAL
TO PARTICIPATE IN THE ANTHRAX VACCINE
IMMUNIZATION PROGRAM

January 1 through December 31, 2001 Separations

Service	Separations	Component	Rank	Total
Army	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Navy	0	Active	n/a	0
	0	Guard	n/a	0
	0	Reserve	n/a	0
Air Force	0	Active	n/a	0
	1	Guard	0-4	1
	0	Reserve	n/a	0
Marines	1	Active	E-3	1
	0	Guard	n/a	0
	0	Reserve	n/a	0

Services Total ----------→ 2

(January 1 through December 31, 2001)

PER (b)(6)

(b)(6)

(b)(6) on 08/19/2003 01:35:50 PM

To: (b)(6)
cc:

Subject: Congressional Mailing List

Per my voice mail - here is the list for reports to Congress. You need to include transmittal letters for the first 8 on the list.

(b)(6)

<<Congressional Mailing List March 24, 2003.doc>>

- Congressional Mailing List March 24, 2003.doc

Coordination of Proposed Report to Congress on Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
OSD, General Counsel	(b)(6)		as revised 6/13/03
Assistant Secretary of Defense (LA)			
Director, Military Vaccines Office			
OSD (OGC)			
Dir, Joint Staff			

Coordination of Proposed Report to Congress on Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
OSD, General Counsel	WBr		
Assistant Secretary of Defense (LA)			
Director, Military Vaccines Office			
OSD (OGC)			
Dir, Joint Staff			

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

August 20, 2003; 10:30 a.m.

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ellen P. Embrey, DASD, (Force Health Protection and Readiness)
//s//7/31/03

SUBJECT: Report to Congress on Separations of Members of the Armed Forces as a Result of a Refusal to Participate in the Anthrax Vaccine Immunization Program for CY 2001 and CY 2002.

- Section 751 of the National Defense Authorization Act for Fiscal Year 2001 requires the Department of Defense to submit to Congress an annual written report on the number of members of the Armed Forces who have been separated as a result of refusing to participate in the Anthrax Vaccine Immunization Program
- TAB A contains the transmittal letters for the chairmen and ranking members of the Senate Armed Services Committee and the House Armed Services Committee.
- TAB B is the report for 2002. During the January 1 through December 31, 2002 reporting period, separation and appeal procedures ended for one servicemember, who was subsequently separated from the Armed Forces.
- TAB C is the report for 2001. During the January 1 through December 31, 2001 reporting period, separation and appeal procedures were completed for two servicemembers who were then separated from the Armed Forces.
- This report has been staffed and coordinated. The Joint Staff revalidated all numbers with the respective Services.

COORDINATIONS: TAB D

RECOMMENDATION: That the ASD (HA) sign the letters at TAB A.

Attachments:
As stated

Prepared by: CDR [redacted] DHSD, (b)(6) [redacted] PCDOCS# 53225

SUBJECT: Report to Congress on Separations as a Result of Refusing to Participate in the AVIP

COORDINATIONS

OSD, General Counsel	(b)(6)	Concur 6/13/03
ASD, LA	USB (initials)	Concur 6/13/03
Director, MILVAX	COL [redacted]	Concur 7/9/03
Director, Joint Staff		Concur
Dir, PI, TMA	(b)(6)	Concur 8/19/03
LA	Lt Col (b)(6)	(b)(6) 8/27/03
CoS, HA	(b)(6)	
PDASD, HA		

Report to Congress on Separations as a Result of Refusing to Participate in the AVIP.

COORDINATION

OSD, General Counsel		Concur
Assistant Secretary of Defense (LA)		Concur
Director, Military Vaccines Agency		Concur
Director, Joint Staff		Concur
Dir, PI, TMA	(b)(6)	[redacted] 8/6 see notes
CoS, HA		_____
PDASD, HA		_____

Coordination of Proposed Report to Congress on Separations that Result from a Refusal to Participate in the Anthrax Vaccine Immunization Program.

COORDINATION

	Concur	Non-concur	Comment
OSD, Office General Counsel			
Assistant Secretary of Defense (LA)			
Director, Military Vaccine Agency	✓		(b)(6) 7/9/03
Dir, Joint Staff			

DOCUMENT MANAGEMENT DIVISION
ADMIN OFFICE

TRICARE
TRICARE Management Activity

ACTION OFFICE DHS DATE 9-3-03 PCDOCS # 53249
Attn: CDR (b)(6) (A) 53225

The attached correspondence is returned for the following reason(s):

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Additional Comments:

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Health Affairs

ROUTING AND TRANSMITTAL SHEET

TRICARE Management Activity

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_____ DASD, HPA			_____ COO		
			_____ Dir, Regional Operations/PEO		
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_____ OGC, DoD			_____ OGC, TMA		
8/27/03 LA		✓			
8/27/03 CoS, HA		✓	_____ Dir, A&M		
_____ Military Assistant			_____ CoS, TMA		
_____ Dir, PI, HA			_____ Dir, PI, TMA CPS 8/28 spk w/ maker		
_____ Dir, P&S			_____ Dir, Admin		
_____ Other (Specify)			_____ Other (Specify)		

CoS 8/28

DMD (SKY)_____ Date:_____ DMD (PNT) A Date: 8/27/03

Date Received: 8/1/03 **Suspense Date:**_____

Subject: RTC on Separations of Members of the Armed Forces as a Result of a Refusal to Participate in AVIP for CY 01+02

PCDOCS #: 53225, 53249 **OSD/P&R #:**_____

AO: CDR (b)(6) **Office:** OHSD **Phone #:** (b)(6)

NOTES: For Dir, PI, TMA Coordination.

Please call (b)(6) for pick up.

(b)(6)

CMAT Control #
2003044-0000049

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(b)(6) **COL, OASD/HA**

From: (b)(6) COL, OASD/HA
Sent: Friday, June 01, 2001 11:03 AM
To: (b)(6)

30

Subject: HA agenda items for JPMPG 6/7

All,

I have 4 agenda items on the next JPMPG meeting agenda - 1) thimerosal containing vaccines in DoD; 2) reporting requirements to local/state health depts; 3) West Nile Virus surveillance; and 4) influenza shortage contingency plan. Unfortunately, I can only be there for about an hour because of another meeting requirement where I'll be representing Dr. (b)(6) I've asked [redacted] to allow me to go 1st at the meeting, and I think that with prior coordination of issues via this email, I should be able to get through my issues in 30-45 minutes. I am attaching pertinent documents for the issue.

ISSUE #1: Thimerosal-containing vaccines in DoD:
a. MMWR, July 09, 1999 / 48(26);563-565; Notice to Readers: Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service. "...Nevertheless, because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible."
b. Need to ensure that MTFs are aware that as thimerosal-free vaccines become available, they should be using up current stocks of thimerosal-containing vaccines and procuring thimerosal-free vaccines for use. Data from DSCP on amount of thim-free vs. thim-containing vaccs being procured is incomplete and not helpful as most vaccines are procured at the local level via prime vendors.
c. Question: Does HA need to send a memo to SGs, or can Services send out info from their level?


mm4826a31-thim.htm


mm4843a41-thim.htm

ISSUE #2: Reporting requirements to local/state health depts.
a. Inquiry from Mr. (b)(6) [Prevention Specialist, Surv Systems Br, CDC Epi Progr Office) concerning federal treatment facilities' reporting of reportable events to local health departments. Jeff provided info on this at last meeting, and I emailed discussions with him on this issue. He would like to provide health departments with copies (or website links) of Service policies re reporting reportable events to local/state health departments. This should not be a problem as I'm pretty sure all Services have some policy re this issue. 2nd request is a little more involved. He would to be able to provide local health departments with a letter template which would be used to notify treatment facilities with reporting requirements. I tend to disagree with this, and would prefer process by which treatment facilities can be made aware of local reporting requirements (eg, via website links, or giving POCs for MTFs). He has presented same issue to VA and other federal facilities.
Mr (b)(6) request:

Good afternoon Col. (b)(6)

You may already have the e-amils below but they should be useful for explaining the background and issues involved in notifiable disease reporting by military bases.

In a nutshell, the problem is that some state and local health departments are not receiving timely and complete notifibale disease data from military bases in their jurisdictions. People in these health departments often do not know the official procedure required to make a standing request for this data, since the procedure varies from one institution to another.

We are asking that the DOD, or each separate branch of the military, provide 1) a document outlining the procedure and all relevant policies, directives, etc., and 2) a template form letter with standardized language that health departments can use to make the standing request.

I do not want or expect this to create more beaurocracy and red tape. Rather, I expect that this will

simply make people at health departments more aware of the existing rules, and how to go about getting data "the right way."

Below are more in-depth descriptions of the issues. Please let me know if you have any questions. Thanks very much; your cooperation is much appreciated!

(b)(6)
MPH
Public Health Prevention Specialist
CDC, Epidemiology Program Office
Division of Public Health Surveillance and Informatics
Surveillance Systems Branch

b. Question: How best to deal with both requests? I'm assuming each Svc already has a policy directing MTFs to ensure that they are fulfilling local public health reporting requirements and therefore we don't need a memo from HA to go out.

ISSUE #3: DoD West Nile Virus Surveillance

a. Last year, HA distributed West Nile Virus Surveillance memo. Memo has been updated and will be resent. Major change is that instead of all findings from installations being given to GEIS (as the DoD POC) where it was compiled then sent to CDC, installations will provide findings to appropriate state dept where it will be included in State data (no installations named) that will be forwarded to CDC. However, installations must provide copies of findings to GEIS who will compile and report DoD findings.

b. Request: please review updated memo. Email or discuss at JPMPG any significant comments. I'd like to send up for signature ASAP. I've included last year's memo for those who did not see it or need a copy.


wnfmemo01.doc


wnfmemo-00.doc

ISSUE #4: DoD Contingency Plan for Flu Shortage

a. Flu program guidance is back to the Services. CDC has not yet decided on implementation of routine vaccinations down to age 55. This will probably be discussed at the ACIP in June. They estimate that it would require at least 10-15 million more doses nationwide. Although there are NO indications at this time that a flu vaccine shortage will/might occur, we should be prepared "just in case". CDC is not only monitoring the vaccine production process, but sending out intermittent influenza updates which I will share with you as they are received. In addition, CDC is also formulating a contingency plan in case of a shortage, and asking the States to prepare conplans.

b. We should also be prepared and I think this involves reviewing last year's DoD memo and revising/updating as the group feels appropriate. This does not have to be done immediately, but over the summer. To my best recollection, we've never had a "lessons learned" discussion.

c. Please review and/or have appropriate others review and provide comments/suggested changes via email to me. I'll bring significant comments to group to discuss via email as needed.


Flu_Pol00.pdf


Flu_Vaccine_Bulletin1.doc


Best Practices-flu.ps

Thanks

(b)(6)
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Program Director, Preventive Medicine & Surveillance
Health Operations Policy
Office of the Assistant Secretary of Defense for Health Affairs
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48

July 09, 1999 / 48(26);563-565

Notice to Readers: *Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service*

The Food and Drug Administration (FDA) Modernization Act of 1997 called for FDA to review and assess the risk of all mercury-containing food and drugs. In line with this review, U.S. vaccine manufacturers responded to a December 1998 and April 1999 FDA request to provide more detailed information about the thimerosal content of their preparations that include this compound as a preservative. Thimerosal has been used as an additive to biologics and vaccines since the 1930s because it is very effective in killing bacteria used in several vaccines and in preventing bacterial contamination, particularly in opened multidose containers. Some but not all of the vaccines recommended routinely for children in the United States contain thimerosal.

There is a significant safety margin incorporated into all the acceptable mercury exposure limits. Furthermore, there are no data or evidence of any harm caused by the level of exposure that some children may have encountered in following the existing immunization schedule. Infants and children who have received thimerosal-containing vaccines do not need to be tested for mercury exposure.

The recognition that some children could be exposed to a cumulative level of mercury over the first 6 months of life that exceeds one of the federal guidelines on methyl mercury now requires a weighing of two different types of risks when vaccinating infants. On the one hand, there is the known serious risk of diseases and deaths caused by failure to immunize our infants against vaccine-preventable infectious diseases; on the other, there is the unknown and probably much smaller risk, if any, of neurodevelopmental effects posed by exposure to thimerosal. The large risks of not vaccinating children far outweigh the unknown and probably much smaller risk, if any, of cumulative exposure to thimerosal-containing vaccines over the first 6 months of life.

Nevertheless, because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers agree that thimerosal-containing vaccines should be removed as soon as possible. Similar conclusions were reached this year in a meeting attended by European regulatory agencies, European vaccine manufacturers, and FDA, which examined the use of thimerosal-containing vaccines produced or sold in European countries.

PHS and AAP are working collaboratively to assure that the replacement of thimerosal-containing vaccines takes place as expeditiously as possible while at the same time ensuring that our high vaccination coverage levels and their associated low disease levels throughout our entire childhood population are maintained.

The key actions being taken are

1. A formal request to manufacturers for a clear commitment and a plan to eliminate or reduce as expeditiously as possible the mercury content of their vaccines.
2. A review of pertinent data in a public workshop.
3. Expedited FDA review of manufacturers' supplements to their product license applications to eliminate or reduce the mercury content of a vaccine.
4. Provide information to clinicians and public health professionals to enable them to communicate

effectively with parents and consumer groups.

5. Monitoring immunization practices, future immunization coverage, and vaccine-preventable disease levels.
6. Studies to better understand the risks and benefits of this safety assessment.

PHS and AAP continue to recommend that all children should be immunized against the diseases indicated in the recommended immunization schedule. Given that the risks of not vaccinating children far outweigh the unknown and much smaller risk, if any, of exposure to thimerosal-containing vaccines over the first 6 months of life, clinicians and parents are encouraged to immunize all infants even if the choice of individual vaccine products is limited for any reason.

While there is a margin of safety with existing vaccines containing thimerosal, there are steps that can be taken to increase that margin even further. Clinicians and parents can take advantage of the flexibility within the existing schedule for infants born to hepatitis B surface antigen (HBsAg)-negative women to postpone the first dose of hepatitis B vaccine from birth until 2 to 6 months of age when the infant is considerably larger. Preterm infants born to HBsAg-negative mothers should similarly receive hepatitis B vaccine, but ideally not until they reach term gestational age and a weight of at least 5.5 lbs (2.5 kg). Because of the substantial risk of disease, there is no change in the recommendations for infants of HBsAg-positive mothers or of mothers whose status is not known. Also, in populations where HBsAg screening of pregnant women is not routinely performed, vaccination of all infants at birth should be maintained, as is currently recommended. In addition to the key actions mentioned above, the PHS Advisory Committee on Immunization Practices and the AAP Committee on Infectious Diseases will be reviewing these issues and may make additional statements.

Reported by: Public Health Service, US Dept of Health and Human Services. American Academy of Pediatrics, Elk Grove Village, Illinois.

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**Questions or messages regarding errors in formatting should be addressed to mmwrq@cdc.gov.

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November 05, 1999 / 48(43);996-8

Recommendations Regarding the Use of Vaccines That Contain Thimerosal as a Preservative

On October 20, 1999, the Advisory Committee on Immunization Practices (ACIP) reviewed information about thimerosal in vaccines and received updates from CDC's National Immunization Program and several vaccine manufacturers on the current and anticipated availability of vaccines that do not contain thimerosal as a preservative. The review was prompted by a joint statement about thimerosal issued July 8, 1999, by the American Academy of Pediatrics (AAP) and the Public Health Service (PHS) (1) and a comparable statement released by the American Academy of Family Physicians (2). These statements followed a Congressionally mandated Food and Drug Administration (FDA) review of mercury in drugs and food, which included a reassessment of the use of thimerosal in vaccines.

Thimerosal is a mercury-containing preservative that has been used as an additive in biologics and vaccines since the 1930s because it prevents bacterial and fungal contamination, particularly in multidose containers. Given the widely acknowledged value of reducing exposure to mercury, vaccine manufacturers, FDA, and other PHS agencies are collaborating to reduce the thimerosal content of vaccines or to replace them with formulations that do not contain thimerosal as a preservative as soon as possible without causing unnecessary disruptions in the vaccination system. FDA will expedite review of supplements to manufacturers' product license applications that present formulations for eliminating or reducing the mercury content of vaccines.

Hepatitis B, DTaP, and Hib Vaccines

A single-antigen, preservative-free hepatitis B vaccine (Recombivax HB[Registered], Merck & Co., Inc., West Point, Pennsylvania)* was licensed on August 27, 1999, and a second hepatitis B vaccine (Engerix-B[Registered], SmithKline Beecham Biologicals, Philadelphia, Pennsylvania) that is preservative-free is under consideration for licensure (3). One manufacturer reported that the supply of its diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine that does not contain thimerosal as a preservative would be sufficient to meet any increased demand during the next year, and three other manufacturers are developing similar DTaP vaccines that could be licensed in the future. Multiple single-antigen *Haemophilus influenzae* type b (Hib) vaccines and the hepatitis B/Hib combination vaccine that do not contain thimerosal as a preservative are licensed, and the supply of these products is adequate to meet national needs.

The risk, if any, to infants from exposure to thimerosal is believed to be slight. The demonstrated risks for not vaccinating children far outweigh the theoretical risk for exposure to thimerosal-containing vaccines during the first 6 months of life.

Given the availability of vaccines that do not contain thimerosal as a preservative, the progress in developing such additional vaccines, and the absence of any recognized harm from exposure to thimerosal in vaccines, hepatitis B, DTaP, and Hib vaccines that contain thimerosal as a preservative can continue to be used in the routine infant schedule beginning at age 2 months along with monovalent or combination vaccines that do not contain thimerosal as a preservative.

Reported failures to vaccinate newborns at high risk for perinatal hepatitis B virus (HBV) transmission suggest that some institutions may have misinterpreted or improperly implemented the recommendations contained in the joint statement by the AAP and PHS--and subsequent clarification-to postpone hepatitis B vaccination only for newborns who are not at high risk (1,3). Chronic HBV infection develops in approximately 90% of infants infected at birth; among chronically infected infants, the risk for premature death from HBV-related liver cancer or cirrhosis is approximately 25% (4). All hospitals and pediatric care providers should ensure that newborn infants receive hepatitis B vaccine as recommended (Table 1) (5). If the supply of single-antigen hepatitis B vaccines that do not contain thimerosal as a preservative is limited, the priority for its use should be to vaccinate newborn infants (3).

Influenza Vaccine

All influenza vaccines contain thimerosal; however, ACIP recommends no changes in the influenza vaccination guidelines, including those for children and pregnant women (6). Evidence suggests that children with certain medical conditions (e.g., cardiopulmonary disease, including asthma) are at substantially increased risk for complications of influenza (7,8). During the influenza season, rates of cardiopulmonary hospitalizations for otherwise healthy women in their second or third trimester of pregnancy are similar to that among persons aged greater than or equal to 65 years who do not have a chronic medical illness and for whom influenza vaccination is also recommended (9). Pregnant women with chronic medical conditions are at higher risk and have a hospitalization rate more than two times greater than among pregnant women without other high-risk medical conditions. A substantial safety margin has been incorporated into the health guidance values for organic mercury exposure developed by the Agency for Toxic Substances and Disease Registry and other agencies (10). ACIP concluded that the benefits of influenza vaccine outweigh the potential risks for thimerosal.

References

1. CDC. Thimerosal in vaccines: a joint statement of the American Academy of Pediatrics and the Public Health Service. MMWR 1999;48:563-5.
2. American Academy of Family Physicians. Policy statement of the American Academy of Family Physicians on thimerosal in vaccines, July 8, 1999. Available at http://www.aafp.org/policy/camp/20.html.
3. CDC. Availability of hepatitis B vaccine that does not contain thimerosal as a preservative. MMWR 1999;48:780-2.
4. Margolis HS, Coleman PJ, Brown RE, Mast EE, Sheingold SH, Arevalo JA. Prevention of hepatitis B virus transmission by immunization: an economic analysis of current recommendations. JAMA 1995;274:1201-8.
5. CDC. Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination: recommendations of the Immunization Practices Advisory Committee. MMWR 1991;40(no. RR-13).
6. CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1999;48(no. RR-4):1-28.
7. Mullooly JP, Barker WH. Impact of type A influenza on children: a retrospective study. Am J Public Health 1982;72:1008-16.
8. Glezen WP, Taber LH, Frank AL, Gruber WC, Piedra PA. Influenza virus infections in infants. Pediatr Infect Dis J 1997;16:1065-8.
9. Neuzil KM, Reed GW, Mitchel EF, Simonsen L, Griffin MR. Impact of influenza on acute cardiopulmonary hospitalizations in pregnant women. Am J Epidemiol 1998;148:1094-102.
10. Agency for Toxic Substances and Disease Registry. Toxicological profile for mercury. Atlanta, Georgia: Agency for Toxic Substances and Disease Registry, 1999.

Table 1

Note: To print large tables and graphs users may have to change their printer settings to landscape and use a small font size.

TABLE 1. Recommendations for hepatitis B vaccination of newborn infants with thimerosal-containing vaccines and vaccines that do not contain thimerosal as a preservative

Mother's HBsAg status at delivery	Recommendation
Positive or Unknown	Vaccinate at birth. Use vaccine that does not contain thimerosal as a preservative; if unavailable, use thimerosal-containing vaccine.
Negative	Vaccinate at birth or by age 2 months. At birth, use vaccine that does not contain thimerosal as a preservative. At 2 months of age, use either thimerosal-containing vaccine or vaccine that does not contain thimerosal as a preservative.
Negative-High-risk*	Same as "Negative" above, except thimerosal-containing vaccine can be administered at birth.

* Populations or groups that have a high risk for early childhood hepatitis B virus (HBV) transmission, including Alaska Natives, Asian-Pacific Islanders, immigrant populations from countries in which HBV is of high or intermediate endemicity, and households with persons with chronic HBV infection.

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MEMORANDUM FOR DEPUTY SURGEON GENERAL OF THE ARMY
DEPUTY SURGEON GENERAL OF THE NAVY
DEPUTY SURGEON GENERAL OF THE AIR FORCE

SUBJECT: West Nile Virus Surveillance for Military Commands and Installations

Since the summer of 1999, West Nile Virus (WNV) encephalitis has become the second leading cause of arboviral encephalitis in the United States. In 1999, 62 cases of severe disease with seven deaths occurred in New York State. In CY 2000, New York, New Jersey and Connecticut reported a total of 21 human cases with two deaths. The case fatality rates are 3-15% with the highest rates in the elderly. The virus was isolated in 2001 from mosquitoes, birds and a variety of mammals along the US east coast from Vermont and New Hampshire in the north to North Carolina in the south. It is expected to continue to spread south and west during subsequent seasons, and all installations should be prepared to assist with surveillance and prevention efforts.

The Centers for Disease Control and Prevention (CDC) coordinated surveillance of mosquitoes, birds and other animals, and humans last year. Surveillance data from military installations were collected weekly by the DoD Global Emerging Infections System (DoD-GEIS) and forwarded to the CDC and presented on the CDC website. Data from DoD installations appeared as part of the state's data in which the installation is located. Last year, five birds from military installations tested positive for WNV – four from West Point, NY and one from Fort Hamilton, NY. One mosquito pool of *Culex* species from Fort Hamilton also tested positive. A report of the accomplishments of the CY2000 surveillance efforts by DoD was published by the US Army Center for Health Promotion and Preventive Medicine (CHPPM) and can be found at http://chppm-www.apgea.army.mil/usachppmtoday/dec1.pdf.

The CHPPM – North detachment will again provide mosquito testing for the DoD. The point of contact to submit specimens for testing is LTC Charles (Gene) Cannon at 301-677-3466 or Mr. Ben Pagac at 301-677-3962. Installations may also submit mosquitoes for testing through state public health laboratories, but should forward any results to the CHPPM – North for inclusion in overall DoD mosquito surveillance reports. Avian morbidity and mortality surveillance will be organized through Veterinary Treatment Facilities. Testing of human specimens is available at the US Army Medical Research Institute of Infectious Diseases (USAMRIID), Fort Detrick, MD or at many state public health laboratories. MTFs may choose to use their state's laboratory for testing, but all specimens should be split with one aliquot forwarded to USAMRIID for testing. The POC at USAMRIID is Dr. George Ludwig at 301-619-4941 or DSN 343-4941.

WNV surveillance data from military installations will continue to be collected in CY2001. Mosquito and bird surveillance will be compiled by CHPPM –North and forwarded to DoD-GEIS for reporting to this Office and the Services. Enhanced passive human surveillance testing will be reported through the installation's preventive medicine

office and forwarded to the DoD-GEIS. POC at DoD-GEIS is Mary Goldenbaum at 301-319-9769, DSN 285.

This year, for inclusion in the CDC database, all WNV surveillance reports (including negative results) need to be reported directly to the appropriate state health department. The state health departments will be responsible for forwarding this information to the CDC. However, all military treatment facilities (MTFs) should report any positive human cases directly to the CDC in addition to reporting them to the state. To assist with planning, the CDC issued updated guidelines in April 2001. This document, "Epidemic/Epizootic West Nile Virus in the United States: Revised Guidelines for Surveillance, Prevention, and Control" can be found on the CDC website at http://www.cdc.gov/ncidod/dvbid/westnile/resources/wnv-guidelines-apr-2001.pdf.

Each Service should develop WNV surveillance and prevention plans applicable for the region and installation. The US Army North Atlantic Regional Medical Command has developed 2001 guidelines that can be used as a general template for other areas. This document and other WNV information and POC listings can be viewed at the DoD-GEIS website at http://www.geis.ha.osd.mil.

RADM J. Jarrett Clinton, MD, MPH, USPHS
Deputy Assistant Secretary of Defense
(Health Operations Policy)

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 2 1 2000

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (MRAI&E)
USCG, DIRECTOR OF HEALTH AND SAFETY
DIRECTOR, TRICARE MANAGEMENT ACTIVITY

SUBJECT: Preparation for Influenza Vaccine Shortage - 2000-2001 Influenza Season

For the 2000-2001 influenza season there will be substantial delay in the availability and therefore a functional shortage of influenza vaccine throughout the United States, including vaccine for the Department of Defense (DoD) and the U.S. Coast Guard. The Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) have developed recommendations for the 2000-2001 influenza season. Their statements on the anticipated shortage do not specifically address military readiness. The Joint Preventive Medicine Policy Group (JPMPG) has adopted the CDC and ACIP recommendations and developed an immunization prioritization plan that balances our primary task to maintain optimal military readiness with our responsibility to protect our most vulnerable populations. For eligible beneficiaries enrolled in DEERS, Military Treatment Facilities and operational force surgeons should prioritize administration of influenza vaccine based on the attached JPMPG recommendations.

The Department will delay organized influenza vaccination campaigns until early to mid-November, pending receipt of adequate supplies of vaccine. Defense Supply Center Philadelphia will provide 50 percent of on hand vaccine to support CINC identified operational requirements. Remaining vaccine will be distributed proportionally to the Services and the Coast Guard based on existing requirements as of 1 September 2000, with 2,500 doses initially held in reserve to address contingency situations including outbreaks or operational deployments. Steps to minimize wastage of vaccine are important, including refraining from placing duplicate orders with multiple companies resulting in the need to return vaccine to manufacturers.

Influenza vaccine prioritization and possible access limitation within DoD and the Coast Guard will necessitate close coordination between Medical and Public Affairs personnel. The TRICARE Management Activity will direct a robust Public Affairs campaign to assure a clear risk communication plan and education of commanders and beneficiaries.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

Attachment:
As stated

cc:
Director Joint Staff
Defense Supply Center Philadelphia
Assistant Secretary of Defense (Reserve Affairs)

Plans for Influenza Vaccine Shortage
2000-2001 Influenza Season

1. For the 2000-2001 influenza season there is an anticipated substantial delay in the availability and therefore a functional shortage of influenza vaccine throughout the United States, including the Department of Defense (DoD) and the U.S. Coast Guard. There are two principal reasons for the shortage:

   a. Lower than expected production yields for the influenza A(H3N2) vaccine component, and

   b. Food and Drug Administration (FDA) manufacturing issues with two of the four companies producing the vaccine, one of which provides the large majority of vaccine (about 2.5 million doses) to the Armed Services.

2. Historically, the military services have used about 2.8 million doses of the vaccine to cover all active duty and eligible vaccine-seeking beneficiaries. There are 230,680 doses at the Defense Supply Center Philadelphia (DSCP) now. Another 2,584,400 doses are expected due by October-November (2,562,800 of these doses depend on when the FDA will allow the manufacturer to release vaccine), and 41,000 doses due by November-December.

3. The following prioritization attempts to balance our primary task to maintain optimal military readiness with our responsibility to protect our most vulnerable populations. Where possible, vaccination of mission critical military personnel and high-risk medical individuals will proceed in parallel (categories 3.a-c). Medically high risk persons will be vaccinated through a process as described in 4.b below, ordinarily by prescription from a military provider until adequate availability of vaccine supply is assured to enable vaccination through standing orders. For eligible beneficiaries, Military Treatment Facilities (MTFs) and operational force surgeons should prioritize administration of influenza vaccine in the following order:

   a. Operational military personnel:

      1) Operational forces forward deployed in support of CINC operational requirements in areas of high security risk (e.g., Southwest Asia, Korea, Eastern Europe) [If vaccine supplies are sufficiently limited to restrict this category, persons stationed in the Pacific should receive higher priority than other geographic areas due to earlier seasonal influenza activity];

      2) Those who are deployed aboard a ship underway for two or more weeks--this may include pre-deployment underway work-up periods and vaccine should be administered at least two weeks prior;

      3) Special duty personnel expected to regularly transit multiple geographic areas or otherwise pose particular operational and epidemiologic risks, such as airlift aircrews and those who are deployed aboard a ship underway. This may include pre-deployment

underway work-up periods. Ideally, vaccine should be administered at least two weeks prior to deployment.

4) Those on 24 hour alert status (Service-specific determination).

b. Health-care workers (including civilian employees and volunteers) with direct patient contact (due to the increased potential to transmit influenza virus infection to high-risk persons);

c. Defense Enrollment Eligibility Reporting System (DEERS) enrollees, whether or not on active duty, with true high risk medical conditions including:

1) Persons over 65 years of age enrolled in TRICARE Senior Prime at an MTF, or who otherwise receive the majority of their medical care at the MTF through an identified primary care manager (PCM) or ongoing patient-provider relationship. [Note reversion to previous age recommendations. This age group historically has about 90% of the mortality from pneumonia and influenza];

2) Adults and children with chronic disorders of the pulmonary or cardiovascular system, including asthma;

3) Adults and children who have required regular medical follow-up or hospitalization during the preceding year for chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus);

4) Residents of long term care facilities (where applicable);

5) Women who will be in the second or third trimester of pregnancy during the influenza season. Pregnant women who have medical conditions that increase their risk for complications from influenza should be vaccinated, regardless of the stage of pregnancy;

6) Children and teenagers (age 6 months to 18 years) who are receiving long-term aspirin therapy, and therefore might be at risk for developing Reye's syndrome after influenza infection.

d. Trainee populations, including basic and advanced trainees, academy students and officer trainees. [These groups are at higher risk for epidemic influenza, but are theoretically easier than operational active duty members to prophylax if necessary with antiviral drugs against influenza A. Epidemiologic data suggest influenza B is less common than influenza A, particularly in these groups, and influenza B incidence usually peaks later in the season when vaccine supplies may be more widely available. Trainee groups should be under special hand-washing precautions at all times to reduce person-to-person transmission of respiratory viruses, including influenza and adenovirus];

e. Other groups in close contact with high-risk persons, such as employees in long term care facilities, household members (age 6 months and older) of high risk patients, and military training instructors;

f. All other military members in priority for deployment;

g. Other active duty members (including Guard and Reserve on active status) and mission critical DoD civilians at OCONUS facilities:

1) Between 50 and 64 years of age
2) Younger than 50 years of age;

h. All other beneficiaries:

1) Between 50 and 64 years of age.
2) Younger than 50 years of age.

Note: This priority scheme may be altered in the occurrence of an epidemic outbreak requiring a focused management effort for a specific population. Alteration of priorities will be at the direction of the Service epidemiology centers and higher headquarters (SG) level preventive medicine authority.

4. The Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) statement on the anticipated shortage does not specifically address military readiness. However, from their recommendation in the 14 July issue of the Morbidity and Mortality Weekly Report (MMWR) (available on line for download at http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4927a4.htm), the following points are relevant:

a. Organized influenza vaccination campaigns should be delayed until early to mid November. Influenza vaccine administered after mid-November will provide substantial protective benefits.

b. Influenza vaccination of persons at high risk (see 3.c. above) for complications from influenza should proceed routinely during regular health-care visits (e.g. clinics, offices, hospitals, nursing homes) as vaccine becomes available. This is particularly important for those young children (age six months to eight years) at high risk who are receiving influenza vaccination for the first time and require two doses, administered at least one month apart.

c. Influenza antiviral drugs are useful for controlling outbreaks in specific and circumscribed situations, but are not recommended for routine, widespread use as chemoprophylaxis against influenza. This is an untested and expensive strategy that could result in many adverse effects.

d. Steps to minimize wastage of vaccine are important, including refraining from placing duplicate orders with multiple companies resulting in the need to return vaccine to manufacturers.

e. Vaccination of health-care workers in direct patient contact is important to reduce transmission to high-risk persons.

5. Influenza vaccine prioritization and possible access limitation within DoD and the Coast Guard will necessitate close coordination between Medical and Public Affairs personnel to assure a clear risk communication plan and education of commanders and beneficiaries.

6. The services will not be able to provide occupational health influenza vaccinations previously provided as a courtesy to DoD civilian employees, except those providing direct patient care and mission critical stationed OCONUS, until such time as a sufficient supply of the vaccine is available. Civilian employees should be directed to their own health care providers, who may also be in a situation of delay and prioritization.

7. The target groups for influenza and pneumococcal vaccination overlap considerably. For persons at high risk who have not previously been vaccinated with pneumococcal vaccine, health-care providers should strongly consider administering pneumococcal vaccine. ACIP recommends that the vaccine be administered to all persons in the following groups: a) persons aged greater than or equal to 65 years, b) immunocompetent persons aged greater than or equal to two (2) years who are at increased risk for illness and death associated with pneumococcal disease because of chronic illness, c) persons aged greater than or equal to two (2) years with functional or anatomic asplenia, d) persons aged greater than or equal to two (2) years living in environments in which the risk for disease is high, and e) immunocompromised persons aged greater than or equal to two (2) years who are at high risk for infection.

   Source: Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). April 04, 1997 / 46(RR-08);1-24
   http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00047135.htm

8. Antiviral drugs are not a substitute for influenza vaccine. Even if an influenza vaccine shortage develops, CDC and ACIP do not support the routine and widespread use of antiviral drugs as chemoprophylaxis against influenza because this strategy is untested, expensive, and could result in large numbers of persons experiencing adverse effects.

   a. Treatment with antivirals is a clinical decision made by the provider and patient. In otherwise healthy individuals already ill with influenza symptoms, these drugs shorten the disease by 24 to 36 hours if started within 48 hours of symptoms. There is no evidence they prevent influenza complications. Therefore, therapeutic use of antivirals should be relatively uncommon and limited to specifically indicated situations.

   b. Prophylactic use of antivirals should be considered for persons at increased risk in accordance with the CDC recommendations and the prioritization scheme above. Presently, the CDC recommends prophylaxis with antivirals for:

1) Persons at high risk who are vaccinated after influenza activity has begun. [Development of antibodies in adults after vaccination can take as long as 2 weeks.]
2) Persons who are unvaccinated and provide care to those at high risk.
3) Persons who have immune deficiency.
4) Persons at high risk who should not be vaccinated.
5) The control of influenza outbreaks in institutions (as in shipboard settings and recruit or trainee populations where epidemic spread is more likely). Antivirals should be continued for at least two weeks or until approximately one week after the end of the outbreak.

Source: CDC. http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/rr4903a1.htm

c. There are currently four drugs available for the treatment of influenza including amantadine, rimantadine, zanamivir, and oseltamivir. Amantadine and rimantadine are used only for influenza A, which occurs more commonly than influenza B. In addition these agents are much less expensive then zanamivir and oseltamivir. The other two agents can be used for influenza A and influenza B. All four agents have been tested for prophylaxis and appear to be effective; however, the FDA has approved only amantadine and rimantadine for influenza prophylaxis. Zanamivir is used as an inhaler, which requires careful patient education and has been reported to cause bronchospasm in patients with asthma. Oseltamivir causes mild gastrointestinal side effects. Amantadine and rimantadine can cause central nervous system (CNS) side effects (12% and 6%, respectively). The incidence of CNS side effects is more frequent in the elderly. Because of the CNS side effects, use of these agents will necessitate flying restrictions in aircrew. Use with caution in other operational personnel. In such situations, rimantadine is preferable to amantadine. Due to its lower cost and the predominance of influenza A, amantadine would be the first-line drug of choice in most other circumstances of use.

d. There is potential for overuse of these drugs, and each MTF should institute measures to ensure proper use. Local outbreaks in institutional settings should also include other public health measures (e.g., hand washing, droplet control, and cohorting).

9. Rapid diagnostics for influenza can aid clinical judgment and help guide treatment decisions, particularly if antivirals are considered for treatment, keeping in mind the benefits of treatment are relatively small. Facilities that use antiviral drugs for treatment may want to use rapid diagnostics to test for influenza. In the presence of an established local epidemic presumptive treatment in patients presenting with influenza-like symptoms may be warranted. Rapid laboratory testing for influenza is available at many MTF's, but there are problems with their use in the clinic setting.

a. As shown in the summary of Rapid Diagnostic Tests, there are sensitivity/specificity differences which may be a consideration in whether to test, and which test to choose. An important consideration in the interpretation of any lab result is the issue of pre-test probability. The predictive value of a positive test is greater in populations with a higher likelihood of disease. In a setting of low influenza prevalence, the positive predictive value

of the rapid tests can be less than 10%. Ensuring that rapid tests are used only in patients exhibiting clinical signs and symptoms suggestive of true influenza will minimize the number of false positive test results. The Febrile Respiratory Illness (FRI) case definition provided below may be helpful in this regard. Keep in mind this case definition helps narrow clinical suspicion for influenza but includes other causes of disease. In the setting of potential outbreaks with limited availability of preventive measures, false positive tests should be avoided to the greatest extent possible. All medical personnel should consider these points in the decision to utilize a rapid diagnostic test.

b. Febrile Respiratory Illness Case Definition

Patient seeking care for the following symptoms within 72 hours of onset.
Fever - Oral temperature $\geq$ 100.5°F (38°C)
and at least one of the following symptoms: cough, sore throat, or headache
or a person with clinical or radiographic evidence of acute, non-bacterial pneumonia

c. Despite the availability of rapid diagnostic tests, the gold standard remains the viral culture, with nasal washings achieving the greatest sensitivity. Only culture isolates can provide specific information on circulating influenza subtypes and strains. This information will also help guide population-based decisions about influenza treatment and prophylaxis. Information regarding virology-capable clinical laboratories within the DoD is available from the epidemiology consultation centers listed in paragraph 9 below. Information on obtaining viral culture media may be obtained through the local clinical laboratory or the DoD Global Influenza Surveillance Program (Air Force is Executive Agent, see contact information in following section).

10. Syndromic surveillance at the local level is the first line of defense against respiratory illness outbreaks. The FRI case definition is a practical starting point in the clinical setting. Recognition of a respiratory illness outbreak requires a heightened awareness on the part of clinicians and preventive medicine/public health officers, with attention to local historical and seasonal illness rates for comparison. Note that increased emphasis on recognition can result in increased reporting rates relative to a previous time of lower emphasis. Close collaboration with local health departments can facilitate recognition of true increases in pathogen activity in the local community. Confirmed influenza cases for reporting should meet the case definition for FRI above along with laboratory verification by culture or rapid diagnostic test. Confirmed influenza cases should be reported promptly through existing service-specific reportable events systems. This information is forwarded to the Service-specific project officer at the central epidemiology and surveillance centers:

- Army — Army Medical Surveillance Activity (AMSA)
  DSN 662-0471 http://amsa.army.mil/AMSA/amsa_home.htm
- Navy — Naval Environmental Health Center (NEHC)
  DSN 253-5500 http://www-nehc.med.navy.mil/index.htm
- Air Force — Institute of Environment, Safety, and Occupational Health Risk Analysis (IERA)

[redacted]

- [redacted]

Influenza Vaccine Bulletin # 1
May 29, 2001

The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) is publishing and distributing a periodic bulletin to update partners about recent developments related to the production, distribution and administration of influenza vaccine for the 2001-2002 influenza season. All recipients of this bulletin are encouraged to distribute each issue widely to colleagues, members and constituents.

$ INFLUENZA VACCINE SUPPLY/PRODUCTION

Influenza vaccine manufacturers periodically update their influenza vaccine production projections.

At different points in the production process, influenza vaccine manufacturers project how much influenza vaccine they are going to produce. Completion of various steps in the manufacturing process provides data that allow the projections to be refined over time. Although still relatively early in the process, all three companies recently provided updated projections which suggest that this year=s production may at least approximate last year=s. Nevertheless, officials at FDA caution that the projections assume that no difficulties are encountered during the remainder of production. They stress that the final yields cannot be known until production is completed.

$ INFLUENZA VACCINE DISTRIBUTION

Annual contingency planning for the possibility of an influenza vaccine production delay or shortfall is essential.

Each year, as new influenza viruses emerge, influenza vaccine manufacturers must produce a new vaccine containing one or more viruses that differ from the previous year=s formulation. Because of the challenges these emergent viruses pose to the vaccine manufacturers and the FDA, and the many other uncertainties inherent in influenza vaccine production, definitive information about annual influenza vaccine production usually will not be available until late summer or early fall. Thus, CDC recommends that all organizations and institutions involved in distributing and administering influenza vaccine annually develop contingency plans. These plans should address problems that would result should a shortfall in vaccine production or a delay in vaccine distribution occur. CDC has asked State health departments to develop plans that include, among other elements, communication with partners and voluntary reallocation of vaccine where needed. The plans will ensure that in the event of a shortfall, vaccine could be targeted to high-risk patients and if distribution of vaccine is delayed, all providers could at least begin their vaccination efforts in their high-risk patients.

A delay in vaccine distribution may impact different providers differently. Providers with high-risk patients should order vaccine now.

Because influenza vaccine is newly produced for each influenza season, numerous factors may affect each manufacturer=s vaccine production and distribution. If some manufacturers are delayed in getting their vaccine to their customers, uneven distribution of the vaccine will result with providers who ordered from one manufacturer possibly receiving vaccine later than providers who ordered from another. Further, providers who order late may receive vaccine late. Providers who order from third party distributors will be dependent upon which manufacturer is supplying that distributor.

If a vaccine shortfall or delay in distribution occurs, mass vaccination clinics should follow the recommendations of the Advisory Committee on Immunization Practices (ACIP) and CDC=s ABest Practices.@

An important change in the ACIP recommendations is to extend the optimal time for vaccinating high-risk individuals from mid-November to the end of November, but realize that immunization attempts should continue into January if necessary. For a copy of the entire ACIP influenza recommendations, please refer to the AResources@ section at the bottom of this bulletin. A copy of CDC=s ABest Practices@ is also attached.

$ INFLUENZA VACCINE COMMUNICATIONS

As the season progresses and more information is obtained regarding influenza vaccine issues, CDC will provide that information at its website at www.cdc.gov/nip/issues/flu.

Resources:

ACIP influenza recommendations:
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5004a1.htm

Flu Best Practices.doc

JPMPG 6/7

Next Mtg: 5 Jul
Withers leaves Jul; repl in 1 Aug

JSI-med surv — JCS Draft & Encl E being circ + meeting in am
- once Encl E final will incorp w/ 8 JSI draft
- JStaff wants to staff to Svcs end of June
w/ possible signature mid-Aug

JSI WG
- met 30 May
- next draft
- 1 more JIWG needed
- (b)(6) [redacted] did brief re endangered vaccine to GEN Peake

Malarone
- MTFs - PEC's DoD Base Core Formulary (no antimal on list)
- add own to meet needs
NMOP - nat mail-order pharmacy
Retail network -
future Uniform Formulary (for NMOP, Retail network)

Pre/Post Depl DMSS
Semi-annual reports from DMSS — ME + send to SVCs + JESS + AFHPC
Policy When set up reg policy to have CoC for products
- Get Semi-annual reports ~~from~~ re pre/post depl
- "Chain of command" for DMSS + report chain to JPMPG. — ME
IMR ConOps (being written by LMI) -
- scannable
- get + distrib Yale Report; ask JPMPG to form ME
Wkgp to review pre/post rept + forms

(2)

Epi X: - List of SOC users to regional & PH agencies
- Questions / issues for CDC POC (Ward)
To Jeff ① PCS of personnel - Office/position access rather than index
② release/use of info (to push to approp persons)
③ Expectations from CDC ~~& message re~~
Tetanus: & army & Navy sent out CDC deferrals for cat V&V
Flu: Southern Georgia issue - ME
JPMPG charter: Who signs charter? NOP or HA ME

Expires 13 July

CMAT Control #
2003043-0000022

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(31)

DRAFT

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (MRAI&E)
USCG, DIRECTOR OF HEALTH AND SAFETY
DIRECTOR, TRICARE MANAGEMENT ACTIVITY

SUBJECT: Preparation for Influenza Vaccine Shortage - 2000-2001 Influenza Season

For the 2001-2002 influenza season there will another delay in the availability of influenza vaccine throughout the United States to include vaccine for the Department of Defense (DoD) and the U.S. Coast Guard. . Although the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) have developed recommendations for the 2000-2001 influenza season, their recommendations do not address military readiness. The Joint Preventive Medicine Policy Group (JPMPG) has adopted the CDC and ACIP recommendations and developed an immunization prioritization plan that balances our primary task to maintain optimal military readiness with our responsibility to protect our most vulnerable populations. For eligible beneficiaries enrolled in DEERS, military treatment facilities and the Services should prioritize administration of influenza vaccine based on the attached JPMPG recommendations.

For the 2001-2002 influenza season, the Department has contracted with Aventis-Pasteur for vaccine. Approximately 754,000 will be shipped to DoD by 14 September 2001 for further distribution. In addition, Aventis has projected that 1.2 million doses will be delivered by 5 October 2001, and the remainder of the 3 million doses ordered by DoD and the USCG will be delivered by 2 November 2001. The Department will delay organized influenza vaccination campaigns until November, pending receipt of adequate supplies of vaccine. Steps to minimize wastage of vaccine are important, including refraining from placing duplicate orders with other companies resulting in the need to return vaccine. to manufacturers.

Influenza vaccine prioritization and possible access limitation within DoD and the Coast Guard will necessitate close coordination between Medical and Public Affairs personnel. The TRICARE Management Activity will direct a robust Public Affairs campaign to assure a clear risk communication plan and education of commanders and beneficiaries.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

Attachment:
As stated

cc:
Director Joint Staff
Defense Supply Center Philadelphia
Assistant Secretary of Defense (Reserve Affairs)

DRAFT

DRAFT

Plans for Delayed Influenza Vaccine Availability
2001-2002 Influenza Season

1. For the 2001-2002 influenza season there is another delay in the production and distribution of influenza vaccine throughout the United States which will affect the Department of Defense (DoD) and the U.S. Coast Guard. There are two principal reasons for the shortage:

   a. A delay in adding additional production capacity for the remaining manufacturers;

   b. Unresolved Food and Drug Administration (FDA) manufacturing issues with some of the manufacturers.

2. Historically, the military services have used about 2.8 million doses of the vaccine to cover all active duty and eligible vaccine-seeking beneficiaries. DoD has ordered almost 3.0 million doses of influenza vaccine for the upcoming season from Aventis-Pasteur. It is anticipated that 25% of the order will be delivered by 14 Sep, 65% by 2 Oct, and the remainder by 2 November.

3. The following prioritization attempts to balance our primary task ~~to~~ of maintain 1st optimal military readiness with our responsibility to protect our most vulnerable populations. Where possible, vaccination of mission critical military personnel and high-risk medical individuals will proceed in parallel (categories 3.a-c). For eligible beneficiaries, Military Treatment Facilities (MTFs) and operational force surgeons should prioritize administration of influenza vaccine in the following order:

   a. Operational military personnel (Service-specific determination):

      1) Operational forces forward deployed in support of CINC operational requirements in areas of high security risk (e.g., Southwest Asia, Korea, Eastern Europe) [If vaccine supplies are sufficiently limited to restrict this category, persons stationed in the Pacific should receive higher priority than other geographic areas due to earlier seasonal influenza activity];

      2) Those who are deployed aboard a ship underway for two or more weeks--this may include pre-deployment underway work-up periods and vaccine should be administered at least two weeks prior; ? to dep

      3) Special duty personnel expected to regularly transit multiple geographic areas or otherwise pose particular operational and epidemiologic risks, such as airlift aircrews and those who are deployed aboard a ship underway. This may include pre-deployment underway work-up periods. Ideally, vaccine should be administered at least two weeks prior to deployment.

      4) Those on 24 hour alert status.

b. Health-care workers (including civilian employees and volunteers) with direct patient contact (due to the increased potential to transmit influenza virus infection to high-risk persons);

c. Defense Enrollment Eligibility Reporting System (DEERS) enrollees, whether or not on active duty, with true high risk medical conditions including:

1) Persons age 65 years of age and older enrolled in TRICARE Senior Prime at an MTF, or who otherwise receive the majority of their medical care at the MTF through an identified primary care manager (PCM) or ongoing patient-provider relationship. [This age group historically has about 90% of the mortality from pneumonia and influenza];

2) Adults and children with chronic disorders of the pulmonary or cardiovascular system, including asthma;

3) Adults and children who have required regular medical follow-up or hospitalization during the preceding year for chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus);

4) Residents of long term care facilities (where applicable);

5) Women who will be in the second or third trimester of pregnancy during the influenza season. Pregnant women who have medical conditions that increase their risk for complications from influenza should be vaccinated, regardless of the stage of pregnancy;

6) Children and teenagers (age 6 months to 18 years) who are receiving long-term aspirin therapy, and therefore might be at risk for developing Reye's syndrome after influenza infection,

d. Trainee populations, including basic and advanced trainees, academy students and officer trainees. [These groups are at higher risk for epidemic influenza, but are theoretically easier than operational active duty members to prophylax if necessary with antiviral drugs against influenza A. Epidemiologic data suggest influenza B is less common than influenza A, particularly in these groups, and influenza B incidence usually peaks later in the season when vaccine supplies may be more widely available. Trainee groups should ~~be under~~ use special hand-washing precautions at all times to reduce person-to-person transmission of respiratory viruses, including influenza and adenovirus];

e. Other groups in close contact with high-risk persons, such as employees in long term care facilities, household members (age 6 months and older) of high risk patients, and military training instructors;

f. All other military members ~~in priority~~ for deployment scheduled for contingencies

g. Other active duty members (including Guard and Reserve on active status) and mission critical DoD civilians at OCONUS facilities:

1) Between 50 and 64 years of age
2) Younger than 50 years of age;

h. All other beneficiaries:

1) Between 50 and 64 years of age.
2) Younger than 50 years of age.

Note: This priority scheme may be altered in the occurrence of an epidemic outbreak requiring a focused management effort for a specific population. Alteration of priorities will be at the direction of the Service epidemiology centers and higher headquarters (SG) level preventive medicine authority.

4. For other recommendations and guidance to include the use of diagnostics and antiviral drugs, and mass immunization campaigns, please refer to the Advisory Committee on Immunization Practices (ACIP) statement on the Prevention and Control of Influenza in the Center for Disease Control and Prevention (CDC) Morbidity and Morbidity and Mortality Weekly Report (MMWR) dated April 20, 2001 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5004a1.htm) and the supplemental recommendations in the MMWR "Notice to Readers" dated July 13, 2001 (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5027a3.htm).

5. Mass vaccination campaigns for lower risk beneficiaries should be delayed until the beginning of November when the remainder of the DoD ordered vaccine is projected to be delivered.

6. Health care providers should be reminded that influenza is a reportable medical event for the DoD Reportable Medical Events System (RMES). Reported cases should meet the definition for a confirmed case of influenza contained in the Tri-Service Reportable Events document which is available on the Army Medical Surveillance Activity website (http://amsa.army.mil/AMSA/amsa_ns_home.htm). Confirmed influenza cases should be reported promptly to the Service surveillance center utilizing existing Service-specific reportable medical events systems.

- Army Army Medical Surveillance Activity (AMSA)
  DSN 662-047 1 http://amsa.army.mil/AMSA/amsa_home.htm

- Navy Naval Environmental Health Center (NEHC)
  DSN 253-5500 http://www-nehc.med.navy.mil/index.htm

- Air Force Institute of Environment, Safety, and Occupational Health Risk Analysis (IERA)
  DSN 240-347 1 http://pestilence.brooks.af.mil/

[redacted]

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2003058-0000011	100	EMAIL DATED JULY 13, 2001 SUBJECT: ADENOVIRUS	1	PDF Image	Highlighted Text	N
2001199-0000018	100	NEWS CLIPS UPDATE, JULY 13, 2001	1	PDF Image	Highlighted Text	N
2003044-0000047	100	ARMED FORCES EPIDEMIOLOGICAL BOARD MEMORANDUM, SUBJECT: PREVENTION/MINIMIZAITON OF ADENOVIRUS INFECTION (DATED 23 NOV 01)	1	PDF Image	Highlighted Text	N
2000347-0000027	100	MEDICAL HISTORICAL ARTICLE ADULT ADENOVIRUS INFECTIONS: LOSS OF ORPHANED VACCINES PRECIPITATES MILITARY RESPIRATORY DISEASE EPIDEMICS	1	PDF Image	Highlighted Text	N
2003041-0000019	97	HA TASKING EMAIL DATED 02/10/2003 SUBJECT: HEARING PAPERS	1	PDF Image	Highlighted Text	N
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2001324-0000013	63	BRIEFING AMERICAN SOCIETY OF TROPICAL MEDICINE AND HYGIENE NOV 13, 2001 GAVE BY DR. KILPATRICK AT A PANEL ON PROTECTING THE HEALTH OF DEPLOYED MILITARY PERSONNEL	1	PDF Image	Highlighted Text	N
		Air Force Joint Instruction 48-110				

1998232-0000013	54	- Immunizations and Chemoprophylaxis - dated November 1, 1995	1	PDF Image	Highlighted Text	N
2003086-0000011	44	NAVAL HEALTH RESEARCH CENTER: IMPACT OF RECENT ADENOVIRUS OUTBREAKS UPON MILITARY TRAINING CENTERS, SEPTEMBER 2000	1	PDF Image	Highlighted Text	N
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2001292-0000043	25	VALERIE GREGG, NEWS MEDIA, MARCH 28, 2000, MILITARY AS DISEASE VECTORS	1	PDF Image	Highlighted Text	N
2001274-0000001	22	SPECIAL REPORT THE PROMISE OF VACCINES WRITTEN FOR THE AMERICAN COUNCIL ON SCIENCE AND HEALTH (ACSH) BY DAVID R. SMITH, M.D., SEPTEMBER 2001	1	PDF Image	Highlighted Text	N
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2003063-0000005	22	ACTION MEMO, FROM COL DINIEGA, HA, SUBJECT: REPRESENTATIVE GILCHRIST'S CONSTITUENT (b)(6) LETTER CONCERNING ADENOVIRUS VACCINE RE: ALLEDGED DOD STOCKPILING OF TETANUS VACCINE	1	PDF Image	Highlighted Text	N
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1999140-0000032	22	Center for Biologics Evaluation and Research, alphabetical list of Biological products by category, 3/3/99	1	PDF Image	Highlighted Text	N
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2003043-0000050	13	INFORMATION FOR RESPONSE TO INQUIRIES ON THE SUBJECT OF DoD ACTION TO OBTAIN A SUPPLY OF ADENOVIRUS VACCINE (U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND PAO)	1	PDF Image	Highlighted Text	N
2000153-0000003	11	RAND DRAFT A REVIEW OF THE SCIENTIFIC LITERATURE ARE IT PERTAINS TO GULF WAR ILLNESSES, VOLUME 1, INFECTIOUS DISEASES, JUNE 2000	1	PDF Image	Highlighted Text	N
2001297-0000038	11	DOD INSPECTOR GENEREAL: REVIEW OF GAO FINAL REPORT, GAO-01-13, COALITION WARFARE, 24 APRIL 2001 GAO CODE 713012	1	PDF Image	Highlighted Text	N
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2001303-0000144	11	PAO NEWS CLIPPINGS, MELODY PETERSEN AND ANDREW POLLACK, NEW YORK TIMES, SEPTEMBER 28, 2001, BIG PUSH TO ACCELERATE VACCINE EFFORT	1	PDF Image	Highlighted Text	N
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		MEDICAL HISTORICAL - MEMBERS OF CONGRESS CONCERNS REGARDING				

1999039-0000013	11	FOLLOWUP QUESTIONS - SENATE COMMITTEE ON VA STAFF PERSIAN GULF WAR ILLNESS RELATED, JULY 8, 1997	1	PDF Image	Highlighted Text	N
1998244-0000021	11	JAMA, August 6, 1997 Vol 278, No. 5, journal of the American medical association, clinical recognition and management of patients exposed to biological warfare agents p. 399	1	PDF Image	Highlighted Text	N
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2003080-0000027	11	BOOK FOR HOUSE VETERANS' AFFAIRS SUBCOMMITTEE ON HEALTH HEARING RE: PERSIAN GULF ILLNESS: HEALTH OF COALITON FORCES, 24 JANUARY 2002	1	PDF Image	Highlighted Text	N
2003085-0000067	11	ARMY FM 8-284: TREATMENT OF BIOLOGICAL WARFARE AGENT CASUALTIES, 29 FEBRUARY 2000	1	PDF Image	Highlighted Text	N
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2002263-0000015	11	NAVY ENVIRONMENTAL HEALTH CENTER, TECHNICAL MANUAL NEHC-TM PM 6490.1 (SEPTEMBER 2000) IMPLEMENTING GUIDANCE FOR DEPLOYMENT HEALTH SURVEILLANCE	1	PDF Image	Highlighted Text	N
2003034-0000015	11	USACHPPM HEALTH INFORMATION OPERATIONS (HIO) UPDATE, 03 JANUARY 2003	1	PDF Image	Highlighted Text	N
1998230-0000018	11	Vaccine Development Overview from the Brown University website	1	PDF Image	Highlighted Text	N
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1998335-0000049	11	HISTORICAL - Vaccines and Disease News	1	PDF Image	Highlighted Text	N
1997226-0000014	11	Journal of the American Medical Association - JAMA, August 6, 1997 - Charlie Holmes	1	PDF Image	Highlighted Text	N
1998216-0000066	6	Infection Control Program in the Air Force Medical Service, AF Regulation 160-41, dated 1 Aug 1989/summary of changes dated 31 Jul 1992	1	PDF Image	Highlighted Text	N
1999203-0000014	6	Accelerated Research Activities for Operation Desert Shield (Naval Medical Research and Development Command)	1	PDF Image	Highlighted Text	N
2001351-0000030	6	BRIEFING DOD GEIS AUG 22, 2001	1	PDF Image	Highlighted Text	N
1998097-0000035	6	USCENTCOM Theatre Medical Surveillance Team, 2nd Rotation, After Action Report, 12 Dec 96 - 20 Mar 97	1	PDF Image	Highlighted Text	N
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OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

JAN 2 8 2003

HEALTH AFFAIRS

MEMORANDUM FOR ~~DEPUTY~~ Anna ASSISTANT TO THE SECRETARY OF DEFENSE (CHEMICAL & BIOLOGICAL DEFENSE)

SUBJECT: Interface with the FDA for Use of Particular IND Products

Dr. Winkenwerder spoke to the Commissioner of the Food and Drug Administration (FDA) and subsequently wrote him a letter on November 20, 2002 (attached). The purpose was to thank the FDA for their efforts since September 11, 2001, to approve drugs and vaccines needed for treatment or prophylaxis of bioterrorism threats and to note that there were several issues that impact our ability for formulate deployment plans for Investigational New Drug (IND) medical products. Specifically, those issues regarding pyridostigmine bromide, botulinum pentavalent toxoid vaccine, and label concerns regarding Anthrax Vaccine Adsorbed (AVA) post exposure with antibiotics and Cidofovir for treatment of smallpox.

The Commissioner of the FDA sent a letter of response dated December 13, 2002 (attached), regarding the use of IND for prophylaxis or treatment to maximize military force health protection capabilities as the war on terrorism and potential new contingencies progress.

Dr. Winkenwerder is sending a response back to the FDA noting that DoD remains eager to work with the FDA to resolve some remaining concerns. Specifically:

a. Pyridostigmine bromide(PB): On January 6, 2003, DoD submitted a New Drug Application (NDA) for PB. Approval of the NDA would eliminate DoD concerns for use of PB under the IND. We await word from FDA Center for Drug Evaluation and Research (CDER) on the approval of the PB NDA.

b. Botulinum pentavalent (BT) toxoid vaccine: We must find a means to provide a limited amount of BT to special units. We are reviewing any other potentially feasible options to address the threat of botulinum toxin. We asked the FDA to continue their stated commitment to work with us to find a resolution to this critically important issue. If this is not a safety issue, can there be a label change or a revision of the informed consent form to allow those who consent to have access to this potentially life saving product?

c. Anthrax vaccine and Cidofovir: FDA replied suggesting that we consider submitting a waiver request with appropriate justification. We agree. We must make such a submission for both of these INDs.

The purpose of this memorandum is to ask you to task the Program Executive Officer for Bio Defense to work with the FDA and USA Medical Research and Materiel Command in an expeditious manner to get approval to use BT in a limited manner for some troops and to provide the required request for waiver for the AVA Post Exposure IND label requirement and the Cidofovir IND label requirement for treatment of smallpox.

My POC is [redacted] (b)(6) Thank you in advance for your willingness to see rapid resolution of these matters.

Sincerely,

Ellen Embrey
Deputy Assistant Secretary of Defense
Force Health Protection and Readiness

Attachments:
As stated

(32) 62

Assistant Secretary of Defense for Health Affairs/Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

House Government Reform Committee

National Security, Emerging Threats, and International Relations

March 25, 2003

House Government Reform Committee
National Security, Emerging Threats, and International Relations
March 25, Hearing
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House Government Reform Committee
National Security, Emerging Threats, and International Relations
March 25, Hearing
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DOD ADENOVIRUS VACCINE STATUS

KEY MESSAGE:

- Adenovirus is a militarily significant respiratory disease that particularly infects military trainees in recruit training camps resulting in respiratory infection, increased burden to the health care system, and lost training time. The company that made the adenovirus vaccine went out of business in 1996. DoD has contracted with another company to re-manufacture adenovirus vaccine.

FACTS:

- Adenovirus vaccines type 4 and type 7 (both oral) were licensed in 1980.
- Army, Navy, and Marine recruits were routinely vaccinated on entry to recruit training camp from 1980 until vaccine supplies were depleted in 1999.
- The manufacturer (Wyeth) ceased producing adenovirus vaccines in 19XX, and the last shipment of vaccine to DoD was in 1996.
- In September 2001, the U.S. Army Medical Research and Materiel Command, awarded a contract to Barr Laboratories, Inc., for the remanufacture of adenovirus type 4 and type 7 vaccines.
- In May 2002, Barr completed an agreement with Wyeth to transfer the manufacturing technology, adenovirus master seeds, and human cell cultures to grow the viruses.
- Barr has broken ground at their Forest, VA facility. Construction of the manufacturing facility will be completed in June 2003 and all equipment will be installed by August 2003.
- Barr estimates that five years will be needed to accomplish development, clinical trials, FDA approval, and establish production capabilities. Upon review of the timelines, no significant cost-effective acceleration of the program could be identified.

COL (b)(6)
FHDAR
(b)(6)
Input from USAMRMC
March 19, 2003

(b)(6) COL, OASD/HA

From: (b)(6) COL, OASD/HA
Sent: Friday, July 13, 2001 9:52 AM
To: (b)(6)

Subject: ebird today - adenovirus

Wall Street Journal
July 13, 2001
Pg. 1

Boot-Camp Bug Returns To The Barracks

When Pentagon Pulls the Plug on Vaccine

By Sarah Lueck, Staff Reporter of The Wall Street Journal

In May 2000, Adam Wood was a healthy 21-year-old shipping off for Navy boot camp in Great Lakes, Ill. Less than two months later Mr. Wood was dead, the victim of a virus caught during training.

The recruit wasn't sickly or weak. His problem appears to have been timing. If he had enlisted two years earlier, he would have received a routine vaccine to protect him from adenovirus, which doctors say most likely caused the viral encephalitis that killed him. But the military stopped giving recruits the vaccine in 1999, after nearly two decades of providing it.

Many people are exposed to adenovirus -- a common germ that causes a range of respiratory illnesses from colds to pneumonia -- without ever getting ill. But the virus poses a unique problem for the military's nine basic-training camps. The combination of cramped living quarters, close contact and stress of boot camp means thousands of the 190,000 recruits who come through each year are far more vulnerable to respiratory illnesses than they would be in civilian settings.

When the vaccine was in use, a busy camp might see as many as 200 cases of respiratory illness a week, fewer than 10% of which were caused by adenovirus, says Margaret Ryan, a Navy health researcher. Without the vaccine, the same camp sees as many as 800 cases of respiratory illness per week, with more than 90% due to adenovirus. During an outbreak last spring at the Army's camp in Fort Benning, Ga., one barrack had to be outfitted as a makeshift infirmary to house recruits that overflowed from the 70-bed hospital. Rates of respiratory illness at the camp were two to four times as high as when the vaccines were in use.

The risks of eliminating the adenovirus vaccine, which has been used solely in military settings, should come as little surprise to the Defense Department. Since the 1950s, the military has known that adenovirus could cause widespread illness during basic training. It has in the past strained medical resources and in rare cases killed otherwise healthy young people. Dozens of military officials and outside advisers had long called for relatively simple measures to keep the vaccine in use. Health experts predicted outbreaks.

Missed Signals

Yet for a decade, because of a series of missed signals and disputes over risks, the Pentagon didn't take steps that would have continued to get the vaccine to recruits at a relatively low cost. The military denied requests from Wyeth Laboratories, the company that has produced the vaccine since the early 1980s, for modest help to keep the vaccine in production. Officials put

off decisions as the same concerns were studied repeatedly. Now, the Pentagon is moving to address the issue, but at a cost
much higher than it would have been if it had acted sooner. Even if the process is successful, the vaccines won't be available for
at least three to five years.

In retrospect, the very success of the adenovirus vaccine appeared to undermine its importance. Some military officials couldn't
fathom that outbreaks would return when they hadn't occurred for decades. Others didn't understand how an infection that generally resembled only a cold could affect the health of recruits and military readiness.

Adenovirus typically causes a cough or sore throat and a fever that last a few days. Some recruits are able to push through training feeling a little sick; others must take a few days of bed rest. As outbreaks have re-emerged, increasing numbers of recruits have fallen behind in training. At Lackland Air Force Base outside San Antonio, for instance, a six-month outbreak last
year forced doctors to work extra shifts and bring in contract nurses to cover a temporary ward. In a typical week, five Lackland recruits must restart training because of lost time; that number increased 20-fold during the outbreak.

Mr. Wood's death is an extreme example of the problems adenovirus can cause. The recruit caught a cold and went to the infirmary three times for help. Others around him were also sick, though not enough in most cases to seek medical treatment.
Dylan Foord, a recruit in Mr. Wood's division, remembers an irritated division commander coming into their barracks one morning and finding so many people coughing that he sprayed Lysol on them. A Navy spokesman says camps frequently use
Lysol as air freshener but couldn't confirm this incident.

Even after several days of being allowed to skip physical exercises, Mr. Wood still had trouble getting up one morning, remembers Mr. Foord, who was suffering from a back injury that also exempted him from exercises: Mr. Wood "couldn't even
stay awake for five minutes. He kept passing out on my shoulder."

Later in the day, Mr. Wood complained that he couldn't see, Mr. Foord says. "He was standing up, feeling around for things."
Mr. Wood became so sick that he was rushed to the hospital in an ambulance, unconscious and suffering from brain seizures.

The recruit's parents, Jim and Sara Wood, drove for 24 hours straight to Great Lakes from a Colorado vacation when they heard their son was near death. "It was the closest to hell I've ever been," Jim Wood says. Adam Wood was in a coma for a
week and quarantined at a Milwaukee hospital because doctors were uncertain what had made him sick. Ultimately, doctors
said his brain had been ravaged. Mr. and Mrs. Wood decided to take their son off his respirator. Two weeks before his division graduated from basic training, Adam Wood's ashes were buried at sea.

Tracking the Cause

An autopsy showed he died from viral encephalitis, or brain swelling. Weeks later, researchers from the military and the Centers for Disease Control and Prevention found evidence of adenovirus in Adam Wood's system, says Dr. Ryan, the Navy
researcher. After ruling out other causes, they concluded adenovirus was the most likely cause of his encephalitis.

Two months after Adam Wood's death, 18-year-old Jess Duden, another Great Lakes recruit, died of respiratory collapse, which military researchers think might have been caused or furthered by adenovirus. The two are believed to be the only recent
recruits who were examined after their deaths for exposure to the virus. Health officials might have determined adenovirus was
a reason for other recruits' deaths if the same tests had been conducted, epidemiologists say.

Death due to adenovirus "is a rare event ... but they're going to happen in ones and twos out there," says Lt. Col. Matthew Dolan, chief of infectious diseases at Lackland's medical center. "If you spin the roulette wheel enough times, you're going to
land on double zero."

The recent surge in adenovirus infections is similar to what the military experienced in the 1960s, when the virus was

found to
be the leading cause of respiratory illness at basic training camps. Government researchers developed two oral vaccines for the
most common types of adenovirus. In 1980, the military contracted with private company Wyeth Laboratories to manufacture
the vaccines solely for recruits, and the Food and Drug Administration approved Wyeth's plant. As the vaccines came into wide use at the training camps, adenovirus outbreaks virtually disappeared.

In 1984, FDA inspectors instructed Wyeth, now a division of American Home Products Corp., to make safety upgrades at the
Marietta, Pa., plant in which it made the adenovirus vaccines. The facility was far from modern. The live adenovirus used in the
vaccines, which was infectious if released, was transported on a gurney. The machine used to make the vaccine tablets was so
outdated that a similar one had been donated to the National Museum of American History in Washington.

Asking for Help

Wyeth asked the Defense Department office in charge of buying supplies for about $5 million to fund an upgrade. A Wyeth spokeswoman says that the market for the adenovirus vaccine -- basic training camps -- was too small to make the vaccine
financially important to the company. Without military funding, she says, Wyeth had no incentive to continue production. The
Philadelphia-based defense office, which handled the contract with Wyeth, asked the Pentagon for more money in its budget,
but the request was turned down. The amount was a minimal part of the military's sprawling budget, but compared with spending on high-profile items such as weapons, it became a low priority.

Over the next decade, Wyeth officials sent "a whole stack of letters" to military officials, warning at first that the company needed money in order to continue producing the vaccines, says Col. Charles Hoke, director of the military's infectious disease
resistance program. When the funding didn't become available, Wyeth warned the Pentagon it would stop production, since the
vaccines weren't profitable. "Wyeth is totally blameless," Col. Hoke says. "They gave us time, and they didn't ask for the sky."

In 1994, the military got a taste of what it would be like without the vaccines. A paperwork glitch disrupted vaccine orders, and
the adenovirus vaccines weren't sent to the training camps for six months. From the summer of 1994 to late 1995, recruits reporting for training in Fort Jackson, S.C., weren't vaccinated. During the peak of infections, nearly 12% of recruits there were
hospitalized every week due to respiratory illnesses caused by adenovirus. It signaled to military preventive-medicine experts
that a bigger problem was on the way. An external advisory group, the Armed Forces Epidemiological Board, told top Pentagon officials in a letter that availability of the vaccines should be given "the highest priority."

A Tougher Job

But by the mid-1990s, making sure there would be a future supply of the vaccines had become more difficult. Wyeth wasn't
willing to keep making the vaccines; it was still under pressure to make FDA-required improvements but wasn't getting Pentagon help to do so. Wyeth was providing vaccine tablets, but it relied on remaining supplies of the live virus and wasn't
producing new stock.

Wyeth agreed to share the technology it had used to make the vaccines with a future manufacturer. But military officials couldn't
find any takers. Vaccines had become a high liability business and the market for adenovirus was tiny. One small company showed interest but ultimately backed out. The issue was at this point "low on the radar screen," says Stephen Joseph, who as
head of the Pentagon's Health Affairs office oversaw the military health budget. "Maybe we should have made it a bigger issue."

In 1998, the Armed Forces Epidemiological Board sent a second letter urging the military to make the vaccines available.

The acting secretary for Health Affairs, Edward D. Martin, told experts who briefed him to study whether using the vaccines would save money.

Philip K. Russell, a retired Army major general who helped develop the vaccines in the 1960s, says the study wasted a year or more and "came out the way everyone predicted," when it showed funding the vaccines would ultimately save money. Dr. Martin says conducting the study, which he says showed the impact of the virus, not cost-effectiveness, did not slow the search for a new vaccine producer.

"The question people would ask is, what would happen if we don't have the vaccine? ... We wanted to convince them," Dr. Martin says.

In August 1998, after Sue Bailey became the Assistant Secretary of Defense for Health Affairs, staff from the Army Surgeon General's office briefed her on adenovirus. Vaccine supplies were dwindling, so Col. Rodney Michael, an infectious-disease expert for the Army, recommended to Dr. Bailey that the Pentagon spend $15 million to $25 million to find a new manufacturer.

'We Felt Like We Had Failed'

Instead, Dr. Bailey suggested further research to determine whether cheaper preventive measures, such as rigorous handwashing and moving recruits' bunks farther apart, could match the vaccines' effectiveness. Advocates of the vaccine were disheartened, feeling there was little evidence such measures were sufficient. "We felt like we had failed, that the message wasn't understood," Col. Michael says.

Dr. Bailey says she stands by her choice, especially since the health budget was tight. "If we do better prevention, rather than spend $15 million for a vaccine for a virus that is not much worse than a bad cold and may not affect our ability to win a war ... you may make as good a dent," she says. "Either I was right, or no one else thought that I was so wrong that they reversed it."

In the past year, pressure to restart vaccine production has been building, especially as word of the outbreaks has spread. Last fall, a strongly worded letter from the Armed Forces Epidemiological Board -- the third the board has sent on the issue -- went out to top military health officials. The board was concerned with the Pentagon's "insufficient recognition" of the problem and the "low priority" given to procurement of the vaccines.

In January 2001, the military asked potential vaccine manufacturers to submit proposals to make adenovirus vaccines -- a far more expensive project now that they must start from the beginning. The future manufacturer will have to conduct research, purchase equipment and gain FDA approval of its plant.

While basic training camps wait for the vaccines, they can do little to prevent future outbreaks. At the army's Fort Leonard Wood, Mo., training camp, drill sergeants have been instructed to allow recruits standing at attention to break position and cover their mouths when they sneeze. At Fort Benning, the adenovirus infirmary is still operating and is primed for expansion should infections increase. Joel Gaydos, a former army preventive-medicine researcher, also raises a "theoretical concern" that adenovirus could become an issue in other military settings such as warships. That's because in the past, by the time troops arrived on board, they would already have been protected by their earlier vaccinations.

At Great Lakes, recruits are being told to wash their hands five times a day, to lessen the spread of adenovirus and other germs. The base reversed a requirement that sinks be dry during inspections so recruits aren't discouraged from washing their

hands. The camp is also considering installing more sinks and providing hand cleaner that doesn't require water when recruits
can't get to sinks. But in the end, says Arlene Hankinson, a preventive-medicine specialist at Great Lakes, vaccines are the only
sure-fire solution.

CMAT Control #
2003044-0000047

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

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(34)

AFEB (15-1a) 02-01

MEMORANDUM FOR The Assistant Secretary of Defense (Health Affairs)
The Surgeon General, Department of The Army
The Surgeon General, Department of The Navy
The Surgeon General, Department of The Air Force

SUBJECT: Prevention/Minimization of Adenovirus Infection

1. On 18 September 2001 the Armed Forces Epidemiological Board (AFEB) was presented with a request from the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to provide recommendations on non-vaccine methods to minimize and control the transmission of adenoviral and other acute respiratory disease-causing agents in the recruit training setting. To assist the Board, the Preventive Medicine officers from the Army, Navy, Air Force, and Coast Guard presented data on respiratory disease incidence at the Service recruit training centers. Dr. Larry J. Anderson from the Division of Viral and Rickettsial Diseases, Centers for Disease Control and Prevention (CDC), presented to the Board CDC's experience with adenovirus outbreaks.

2. The Board continues to be deeply concerned about the loss of adenovirus vaccine for use in the basic training setting and the resultant increase in acute respiratory illnesses (ARI) among basic trainees at several basic training sites across the military services. The rates of ARI and disease impact appear to be uneven from site to site, but sustained increases in disease have been observed since the loss of the adenovirus vaccine at several U.S. Army basic training posts, Great Lakes Naval Training Center, Lackland Air Force Base, and the U.S. Coast Guard Training Center Cape May. Increased ARI in the basic training setting is far more than an inconvenience. It has resulted in increased utilization of outpatient medical care, increased numbers of hospitalizations, one to several missed days of training for affected recruits and resultant "recycling" of some basic trainees, and most tragically, two adenovirus related deaths among U.S. Navy recruits.

3. Recent events in New York, Washington DC, and Pennsylvania, as well as the numerous anthrax cases, carry the potential for a protracted military response over the coming months and years. This may result in increased numbers of basic trainees processing through existing recruit training sites which are already at times overcrowded. This combination of factors increases the likelihood for even greater problems associated with ARI than currently observed, as ARI transmission is enhanced by crowded conditions. ***Therefore, the Board feels that this issue goes beyond traditional public health concerns and should be viewed as having the potential to jeopardize operational military readiness, as it did in the early and mid-20th century.***

4. There appears to be a wealth of historical epidemiologic data, both from studies done in the pre-vaccine era and from studies of more recent outbreaks. In addition, there are intriguing patterns suggesting significant differences in the incidence of ARI across the basic training sites. It is possible that some of these differences are explained by differential case ascertainment and application of case-definition, but these are unlikely to explain the magnitude of the differences. Well designed and executed hypothesis driven research studies examining potential factors associated with endemic and epidemic disease occurrence in some settings, and the lack of epidemic disease in others, clearly need to be performed.

5. Based on currently available information, the Board makes the following recommendations:

a. THE SINGLE GREATEST PRIORITY IS TO REESTABLISH A STABILE SUPPLY OF ADENOVIRUS VACCINE AS SOON AS POSSIBLE. IT IS UNLIKELY ANY SINGLE INTERVENTION OR COMBINATION OF INTERVENTIONS WOULD BE AS EFFECTIVE IN THE BASIC RECRUIT TRAINING SETTING AS THE ADENOVIRUS VACCINE HAS BEEN IN REDUCING ARI. IT IS UNCLEAR TO THE BOARD WHY IT HAS BEEN ESTIMATED TO TAKE AS LONG AS 6-8 YEARS TO ESTABLISH A NEW SUPPLY OF VACCINE, SINCE THE EXISTING VACCINE IS AN ALREADY FOOD AND DRUG ADMINISTRATION APPROVED AND LICENSED PRODUCT.

b. THE BOARD IS CONCERNED THAT AN EXAMINATION OF NON-VACCINE/NON-ANTIMICROBIAL METHODS TO REDUCE ARI TRANSMISSION, WHILE UNDERSTANDABLE IN THE ABSENCE OF ADENOVIRUS VACCINE, MAY RESULT IN A PERCEPTION BY THE MILITARY SERVICES THAT THESE METHODS REDUCE THE URGENCY OF OBTAINING A SUPPLY OF ADENOVIRUS VACCINE, AND MIGHT EVEN SUBSTITUTE FOR IT AND OTHER VACCINES. EVEN FOR THE BEST STUDIED AND MOST WIDELY USED OF THESE PRACTICES - HAND WASHING AND BUNK SPACING - THERE IS LIMITED EVIDENCE THAT NON-VACCINE METHODS ARE EFFECTIVE. MUCH OF THAT EVIDENCE IS OLD AND MAY NOT BE VALID IN THE CURRENT RECRUIT TRAINING ENVIRONMENT. NON-VACCINE METHODS ARE FLAWED BECAUSE THEY ABSOLUTELY DEPEND ON THEIR CONSCIENTIOUS, CONTINUOUS, AND PERSISTENT APPLICATION. THE CULTURE NECESSARY TO ACHIEVE THIS IS EXTREMELY DIFFICULT TO SUSTAIN UNDER THE PRESSURES AND DEMANDS OF RECRUIT TRAINING, AND THE CONTINUOUS TURNOVER OF THOSE WHO CONDUCT THE TRAINING. THEREFORE, THE BOARD EMPHASIZES THAT NON-VACCINE/NON-ANTIMICROBIAL METHODS ARE NEVER A SUBSTITUTE FOR VACCINES AND ARE, AT BEST, A STOP-GAP MEASURE.

c. RESEARCH EFFORTS SHOULD BE DIRECTED TOWARDS THE STUDY OF ANTIMICROBIAL/ANTIVIRAL COMPOUNDS AND VACCINES OTHER THAN ADENOVIRUS, MENINGOCOCCAL, AND INFLUENZA WHICH MAY BE EFFECTIVE FOR PREVENTION, PROPHYLAXIS OR TREATMENT OF ARI IN THE RECRUIT SETTING INCLUDING DISEASE OUTBREAKS.

d. AMONG ALTERNATIVE COUNTERMEASURES (ADMINISTRATIVE, PERSONAL HYGIENE, ENVIRONMENTAL, AND ENGINEERING), THE TWO THAT APPEAR TO HAVE BEEN THE BEST STUDIED AND HOLD THE MOST PROMISE IN REDUCING THE BURDEN OF ARI ARE HANDWASHING/PERSONAL HYGIENE AND BUNK SPACING. HOWEVER, MANY OF THE STUDIES ON THESE MEASURES TOOK PLACE DECADES AGO, AND IT IS UNCLEAR HOW APPLICABLE THEY ARE TO TODAY'S MILITARY BASIC TRAINING SETTING. A DETAILED REVIEW OF THE HISTORICAL AND CURRENT DATA ON THESE TWO INTERVENTIONS (INCLUDING SPECIFIC STUDIES AND OUTBREAK INTERVENTIONS) SHOULD BE CONDUCTED, SUMMARIZED INTO A SINGLE DOCUMENT, AND PRESENTED TO THE BOARD IN ORDER THAT MORE SPECIFIC RECOMMENDATIONS FOR THEIR APPLICATION IN THE BASIC TRAINING SETTING CAN BE MADE.

e. IF A RECOMMENDATION IN FAVOR OF ANY OF THE ABOVE COUNTERMEASURES IS MADE, THERE MUST BE A MECHANISM AND THE NECESSARY RESOURCES AVAILABLE TO ASSURE THEY ARE APPROPRIATELY ADOPTED AND IMPLEMENTED BY THE VARIOUS SERVICES AND AT ALL MILITARY BASIC RECRUIT TRAINING SITES.

f. PENDING MORE SPECIFIC RECOMMENDATIONS, ALL BASIC TRAINING SITES SHOULD PROVIDE AMPLE OPPORTUNITIES FOR AND ENCOURAGE FREQUENT HAND WASHING (OR COMPARABLE METHODS) AND PERSONAL HYGIENE AMONG BASIC TRAINEES. ALL SITES SHOULD PROVIDE TISSUES TO TRAINEES TO COVER THEIR NOSES AND MOUTHS WHEN SNEEZING OR COUGHING, AND ALLOW TISSUES TO BE CARRIED AS NECESSARY. ATTITUDES AND BARRIERS THAT DISCOURAGE THESE ACTIVITIES SHOULD BE ELIMINATED BY COMMAND POLICY AND COMMAND ENFORCEMENT.

g. OTHER COUNTERMEASURES (E.G. BENZATHINE PENCILLIN FOR CIRCUMSTANCES OTHER THAN CONTROLLING GROUP A STREPTOCOCCAL DISEASE, ENHANCED VENTILATION, ULTRAVIOLET LIGHT) APPEAR TO HAVE BEEN BENEFICIAL IN LIMITED CIRCUMSTANCES OR HAVE NOT BEEN DEMONSTRATED TO BE EFFECTIVE. THE BOARD IS CONCERNED THAT ANY

APPARENT BENEFIT COULD REPRESENT CONFOUNDING FROM OTHER UNRECOGNIZED INTERVENTIONS AND IS RELUCTANT TO ENDORSE THESE OTHER COUNTERMEASURES UNLESS MORE DEFINITIVE DATA ARE AVAILABLE.

h. THE UNCERTAINTY REGARDING ALTERNATIVE COUNTERMEASURES HIGHLIGHTS THE CRITICAL NEED FOR WELL DESIGNED AND EXECUTED HYPOTHESIS DRIVEN RESEARCH STUDIES OF THEIR IMPACT. CURRENTLY AVAILABLE DATA SUGGEST THAT ARI RATES, AND THE PROPORTION CAUSED BY ADENOVIRUS, VARY WIDELY AMONG THE TEN MAJOR BASIC RECRUIT TRAINING SITES. IN ADDITION, OTHER WESTERN MILITARIES WHICH DO NOT ROUTINELY USE ADENOVIRUS VACCINE APPEAR NOT TO HAVE A PROBLEM OF SIMILAR MAGNITUDE. THE REASONS FOR THESE DIFFERENCES NEED TO BE ELUCIDATED THROUGH WELL-DESIGNED AND EXECUTED EPIDEMIOLOGIC STUDIES.

i. THE LOSS OF ADENOVIRUS VACCINE AND SUBSEQUENT RISE IN ARI MAKES IT ESPECIALLY IMPORTANT TO ASSURE A STEADY SUPPLY OF VACCINES FOR OTHER RESPIRATORY DISEASES WHICH HAVE HISTORICALLY BEEN PROBLEMATIC IN THE RECRUIT TRAINING SETTING, PARTICULARLY INFLUENZA AND MENINGOCOCCAL DISEASE. THE BOARD IS CONCERNED THAT EFFORTS TO TRANSITION TO A CONJUGATE MENINGOCOCCAL VACCINE COULD POTENTIALLY DISRUPT VACCINATION EFFORTS IN THE FUTURE, AND RECOGNIZES THE PROBLEMS WITH OBTAINING AN ADEQUATE SUPPLY OF INFLUENZA VACCINE EACH OF THE LAST TWO INFLUENZA SEASONS.

6. For more definitive recommendations to be made on the efficacy of handwashing/personal hygiene and bunk spacing in preventing ARI in the basic recruit training setting, the Board requests that Health Affairs provide a review of historical and contemporary data on efficacy of handwashing/personal hygiene and bunk spacing and a summary of the ARI outbreak investigations that have been performed at the basic recruit training sites at the next meeting of the AFEB. Dr. Anderson from the Division of Viral and Rickettsial Diseases, Centers for Disease Control and Prevention (CDC), has offered to provide an Epidemic Intelligence Service Officer to assist in assessing available data on the differences in site disease occurrence. Additionally, the Board would like a current status report at the next meeting on the adenovirus vaccine issue, particularly the status of vaccine production and projected timelines and an update on research efforts directed towards the study of antimicrobial/antiviral compounds and vaccines which may be effective in prevention, prophylaxis or treatment of ARI in the basic recruit training setting.

AFEB (15-1a) 02-01
SUBJECT: Prevention/Minimization of Adenovirus Infection

7. The above recommendations were unanimously approved.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

STEPHEN M. OSTROFF, M.D.
AFEB, President

JAMES R. RIDDLE, D.V.M., M.P.H.
Lt Col, USAF, BSC
AFEB Executive Secretary

Encl
ASD(HA) Memorandum dated 8 August 2001

CF:
Board Members and Consultants (w/encl)
USAMRMC (w/encl)
USAMRIID (w/encl)
USD (AT&L) (w/encl)
Joint Vaccine Acquisition Program (w/encl)
J4-MRD (w/encl)

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THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

AUG 8 2001

MEMORANDUM FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Prevention/Minimization of Adenovirus Infection

Historically, the Armed Forces Epidemiological Board (AFEB) has been very helpful in making recommendations to the Department of Defense (DoD) and the Services concerning the prevention and/or minimization of diseases. As the Board is well aware, adenovirus vaccines (Type 4 and Type 7) were used in Army, Navy, and Marines Corps recruit training facilities as the primary means of preventing the transmission of adenovirus Types 4 and 7. The Board is also aware that vaccine production was discontinued in 1996, and the DoD subsequently took action to extend the use of remaining vaccines and to find another manufacturer for adenovirus vaccines. It is estimated, however, that it may be several years before the adenovirus vaccines will be available.

Despite these complexities, the Department must continue in its disease control efforts against adenovirus and other acute respiratory diseases. Therefore, I request the assistance of the AFEB in conducting a thorough review of known and suggested non-vaccine methods to minimize and control the transmission of adenoviral and other acute respiratory disease-causing agents in the recruit training setting. This review should address all possible alternative countermeasures, including administrative, personal hygiene, environmental, and engineering methods. This review should conclude with a report on recommendations from the Board on potentially effective non-vaccine methods that may be considered for testing, targeted uses (e.g., seasonally, during outbreaks). or general implementation at recruit training facilities to minimize/prevent the transmission of adenovirus infections.

I request that you address this issue at your next AFEB meeting in September 2001, and provide the results of your review within 75 days of this meeting.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

CMAT Control #
2003041-0000019

35 67

[redacted] on 02/10/2003
12:50:43 PM

To: (b)(6)
cc: [redacted]

Subject: FW: Hearing Papers

(b)(6) See below - I've typed in POCs next to the topic.

-----Original Message-----
From: (b)(6)
Sent: Monday, February 10, 2003 12:17 PM
To: [redacted]
Cc: (b)(6)
Subject: Hearing Papers
Importance: High

We are beginning to prepare Dr. Winkenwerder for Congressional Oversight hearings in the near future. In order to facilitate this preparation, we are requesting that you provide information papers on the below subjects. A sample format is attached; the "key messages" should be a description of the message that Dr. Winkenwerder should be prepared to communicate to Congress; please keep any background or factual information in the "facts" section of the paper.

Please submit papers to me (please copy [redacted] no later than 1200, Wednesday, February 19th.

Papers that were previously submitted for Secretary Rumsfeld or Dr. Chu's hearing preparation are highlighted in yellow and are attached. Please resubmit these in the requested format and include any additional or updated information as appropriate.

Please call or email me with any questions or concerns.

Thank you.

V/R
(b)(6)
Force Health Protection (DHS) — [redacted]
Anthrax (b)( ) — (b)(6)
Adenovirus (b)(
DoD Role i[redacted] — (b)(6)
Smallpox (b)(6)
SHAD (DHS
Gulf War Illness (ALS Study) (DHS) — (b)(6)
Pre and Post Deployment Health Assessments (DHS) — (b)(6)
Environmental Surveillance (DHS) — (b)(6)
Depleted Uranium (DHS) — (b)(6)
Pyridostigmine Bromide (b)(6)
Iowa Army Ammunition Plant (b)(6) (DHS???) — (b)(6)

<<Sample.doc>> <<SecDef Smallpox.doc>> <<Force Health Protection.doc>>
<<PB.doc>> <<Project112 SHAD Info Paper.doc>> <<Anthrax.doc>>

[redacted]
Office of the Assistant Secretary of Defense (Health Affairs)

TRICARE Management Activity

[redacted]

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- Pre-PostDeployAssess.doc
- SecDef Smallpox.doc
- Force Health Protection.doc
- PB.doc
- Project112 SHAD Info Paper.doc
- Anthrax.doc

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DOD ADENOVIRUS VACCINE STATUS

KEY MESSAGE:

Adenovirus is a military significant respiratory disease that particularly infects military trainees in recruit training camps resulting in respiratory infection, increased burden to the health care system, and lost training time. The military Services required recruits to be vaccinated with adenovirus vaccine Type 4 and 7 between 1980 until 1999 when vaccine supplies were depleted. The company which made the adenovirus vaccine went out of business in 1996. DoD has contracted with another company to re-manufacture adenovirus vaccine.

FACTS:

- Adenovirus vaccines Type 4 and 7 (both oral) were licensed in 1980.
- Army, Navy, and Marine recruits were routinely vaccinated on entry to recruit training camp from 1980 until vaccine supplies were depleted in 1999.
- The manufacturer (Wyeth) ceased producing adenovirus vaccines in 19XX, and the last shipment of vaccine to DoD was in 1996.
- In September 2001, the US Army Medical Research and Materiel Command, awarded a contract to Barr Laboratories, Inc for the remanufacture of the adenovirus types 4 and 7 vaccines.
- In May 2002, Barr completed an agreement with Wyeth to transfer the manufacturing technology, adenovirus master seeds, and human cell cultures to grow the viruses.
- Barr has broken ground at their Forest, VA facility. Construction of the manufacturing facility will be completed in June 2003, and all equipment will be installed by August 2003.
- Barr estimates that 5 years is needed to accomplish development, clinical trials, FDA approval, and establish production capabilities. Upon review of the timelines, no significant cost-effective acceleration of the program could be identified.

Prepared by: COL [redacted] FHP&R [redacted] Input from USAMRMC/February 13, 2003

36 69

Assistant Secretary of Defense for Health Affairs/Special Assistant for Gulf War Illnesses, Medical Readiness, and Military Deployments

House Committee on Veterans Affairs Health Subcommittee

March 27, 2003

House Committee on Veterans Affairs (HVAC)
Health Subcommittee March 27, 2003 Hearing

Table of Contents

House Committee on Veterans Affairs (HVAC)
Health Subcommittee March 27, 2003 Hearing

Table of Contents (Continued)

DOD ADENOVIRUS VACCINE STATUS

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COL [redacted]
EHP&R
[redacted]

Input from USAMRMC
March 19, 2003

71

HA/TMA Document Profile

45753

Subject: Alleged DoD Stockpiling of Tetanus Vaccine

Author: Gilchrest, Wayne T. MOC
Congressional Name: Gilchrest, Wayne T. MOC
Date of Document: 11/22/2002
Input By: (b)(6)
OSD # : U 01811-03
Profiler's Directorate: Admin, HA
PR # :
Response Signed By:
Organization: Congress of the United States
Dt Response Signed:
Department: House of Representatives
Doc Type: 102-18
Assigned To: DHS
Application: DOCSIMAGE
Prepared For: DASD
Previous Documents:
Suspense Date: 3/4/2003
Related Documents:
Coord Office(s):
Notes:

Beneficiary Info
Beneficiary Name: [redacted]
Address 1:
Apartment #
Phone #
Email Address:
City:
State: Zip

History
Created: 2/10/2003 HA PCDOCS Adr
Edited: 2/10/2003 HA PCDOCS Adr
Status: Available

Retention Schedule
Type: Keep

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Access Control
☒ Secure Document
☐ Enable Content Searching

3014-002

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OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

ACTION MEMO

January 9, 2003 2:00 PM

FOR: ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

FROM: Ms. Ellen P. Embrey, DASD (Force Health Protection and Readiness) for

SUBJECT: Designation of Protocols as "Contingency Investigational New Drug (IND) Protocols for Force Health Protection"

- Attached at TAB A is a draft policy memorandum that designates six Investigational New Drug (IND) protocols as "Contingency IND Protocols for Force Health Protection."
- With the designation of "Contingency IND Protocol for Force Health Protection," the protocols listed in this memorandum will be subject to DoD Directive 6200.2 (Use of INDs for Force Health Protection), which requires approval by the Army Surgeon General's Institutional Review Board (IRB).
- For coherence, consistency, and efficient implementation, the Army's IRB, known as the Human Subjects Research Review Board (HSRRB), is designated in DoD 6200.2 (TAB B) as the centrally approving IRB that will be the approving authority for all of the Services Contingency IND Protocols.
- Local Army, Navy, Air Force and Marine Clinical Investigation Program (CIP) IRBs may individually review the Contingency IND Protocols for Force Health Protection, but will not be able to modify them.

RECOMMENDATION: That the ASD (HA) sign memo at TAB A.

COORDINATION: TAB C

Attachments:
As stated

Prepared by: CDR (b)(6) DHSD, [redacted] PCDOCS# 44755, 44756

[redacted]

[redacted]

(b)(6)

[redacted]

OGC

SUBJECT: Designation of Protocols as "Contingency Investigational New Drug (IND) Protocols for Force Health Protection"

COORDINATIONS

USAMRMC	LTC (P) (b)(6)	Concur 01/09/03
Deputy Director, DHSD	(b)(6)	Concur 01/09/03
CoS (HA)	(b)(6)	
PDASD (HA)	(b)(6)	
OGC	(b)(6)	