The following is a map and copy of my BCNR package for use by any similarly situated servicemen and women who were unjustly punished for refusing Anthrax. I have enclosed it here for your use to help make your work easier in duplicating my success.

Because it has been redacted and edited for brevity, below is a map of the contents to help understand the rationale for inclusion of each item. Some of the items are not in the version that I have publicly shared on this website.

It is my hope that future submissions will not need to be so wordy. My full submission including addendums was 244 pages.

Please feel free to reach out to the owner of this website. He and I will be glad to help you as much as we can.

To you success,
James D. Muhammad
Sergeant, USMC (Veteran)

1. DD-149
    - Ensure that you have the latest version when submitting and it is completely filled out and signed
2. Because my issues were too numerous to fit on the form, I included an attachment to explain Block 5
    - Each grievance or error was given a separate numbered line item
3. Because my issues were too numerous to fit on the form, I included an attachment to explain Block 6
    - Each was given a separate bullet point
    - The attachment was put into chronological form and served as an overview of the package contents
    - Most items were annotated by footnote to indicate where it was located in the package with relevant passages in the body of the text
    - Each page of the package was numbered in the bottom right corner using a Bates numbering scheme to make it easy for the Board to find any page or footnote reference. I used the format of FLNAME-BCNR-xxx where FLNAME is my first initial and last name and xxx is the sequential page number of the package
4. Attachment for explanation of Block 9; because I included a lot of artifacts, I felt this was necessary to help give context to each document included
5. Table of Contents so Board members will have a title for each document and have another place to know where to find it based on Bates number.
    - Each package is reviewed by a group of 3 persons and they talk about their findings. It's helpful if a board member likes a particular artifact and can reference it easily for the others. The contents are as follows:
        - DD-214

- Sentencing given
- Doe v Rumsfeld filing 20031222
- Enlistment contract
- Record of PME
- Recommendation Letters collected while on Active Duty
- Documentation of Refusal of AVIP
- 20041027 Doe v Rumsfeld
- Memo: Implementation of AVIP under EUA
- 20050406 Doe v Rumsfeld
- 20060209 Doe v Rumsfeld
- NMCCA Opinion US v Muhammad
- 20061012 AVIP Resumption letter
- 20070821 Doe v Rumsfeld
- Other Board of Correction cases (5)
- LES
- US Supreme Court Case Little v Barreme (to refute NMCCA Opinion on inherent orders and using US v Kisala as precedent ruling)
- Stripes article: Lt. Col Lacken, USAF
- NAMALA DNA Collection Order
- Picture collage (redacted in public version)
- Personal and Professional Biography demonstrating how my life has evolved since SCM
- Professional and other Certificates
- Letters of Support (13), including updates from persons who wrote letters during trial
- Records of accomplishments during service
- Copy of SMART Transcript
- Deployment Roster showing that I removed from deployment for Anthrax refusal despite policy to the contrary
- Meritorious Commissioning (MCP) documents and questions

6. BCNR Addendum March 2019
    - Explanation regarding Memo (next item)
        - Includes a Point by Point explanation of which parts I believe I qualify for
        - Includes changes to UCMJ that would show beneficial
    - Memo for Secretaries of the Military Departments: Guidance of Military Discharge Review Boards and Board for Correction fo Military/ Naval Records Regarding Equity, Injustice or Clemency Determinations (Jul 25, 2018)
    - AVA Package Insert
7. BCNR Addendum May 2019
    - This addendum was related to my sldelined MCP package and would not ordinarily need to be included in a BCNR packages but it was addressed to demonstrate the potential the Marine Corps missed by discharging me from service

Application
Board of Correction of Naval Records
for
James D Muhammad, USMC

APPLICATION FOR CORRECTION OF MILITARY RECORD UNDER THE PROVISIONS OF TITLE 10, U.S. CODE, SECTION 1552

(Please read Privacy Act Statement and instructions on back BEFORE completing this application.)

OMB No. 0704-0003
OMB approval expires Dec 31, 2017

RETURN COMPLETED FORM TO THE APPROPRIATE ADDRESS ON THE BACK OF THIS PAGE.

1. APPLICANT DATA *(The person whose record you are requesting to be corrected)*

a. BRANCH OF SERVICE *(X one)*		ARMY		NAVY		AIR FORCE		MARINE CORPS		COAST GUARD

b. NAME *(Print - Last, First, Middle Initial)*	c. PRESENT OR LAST PAY GRADE	d. SERVICE NUMBER *(If applicable)*	e. SSN
Muhammad, James D	E-1	none	[redacted]

2. PRESENT STATUS WITH RESPECT TO THE ARMED SERVICES *(Active Duty, Reserve, National Guard, Retired, Discharged, **Deceased**)*	3. TYPE OF DISCHARGE *(If by court-martial, state the type of court)*	4. DATE OF DISCHARGE OR RELEASE FROM ACTIVE DUTY *(YYYYMMDD)*
Discharged	SCM, BCD	20070302

5. I REQUEST THE FOLLOWING ERROR OR INJUSTICE IN THE RECORD BE CORRECTED AS FOLLOWS: *(Entry required)*

Summary
Applicant requests the board to investigate an administrative error that amounted to unjust delay in applicant's career progression and graduation from Officer Candidate School.
Applicant wishes to request equitable relief due to career being sidelined due to refusal to take Anthrax Vaccine.
Verbose request in attachment

6. I BELIEVE THE RECORD TO BE IN ERROR OR UNJUST FOR THE FOLLOWING REASONS: *(Entry required)*

Applicant was unjustly and administratively improperly removed from consideration for selection to the Meritorious Commissioning Program (MCP)
Applicant was unjustly and excessively punished for refusal to accept Anthrax Vaccine.
Verbose discussion in attachment

a. IS THIS A REQUEST FOR RECONSIDERATION OF A PRIOR APPEAL?		YES	b. IF YES, WHAT WAS THE DOCKET NUMBER?	c. DATE OF THE DECISION
		NO	none	none

7. ORGANIZATION AND APPROXIMATE DATE *(YYYYMMDD)* **AT THE TIME THE ALLEGED ERROR OR INJUSTICE IN THE RECORD OCCURRED** *(Entry required)* 20030409 [redacted] BN [redacted] Camp Lejeune, NC; 20070320 NAMALA

8. DISCOVERY OF ALLEGED ERROR OR INJUSTICE

a. DATE OF DISCOVERY *(YYYYMMDD)*	b. IF MORE THAN THREE YEARS SINCE THE ALLEGED ERROR OR INJUSTICE WAS DISCOVERED, STATE WHY THE BOARD SHOULD FIND IT IN THE INTEREST OF JUSTICE TO CONSIDER THE APPLICATION.
20180410	none

9. IN SUPPORT OF THIS APPLICATION, I SUBMIT AS EVIDENCE THE FOLLOWING ATTACHED DOCUMENTS: *(If military documents or medical records are pertinent to your case, please send copies. If Veterans Affairs records are pertinent, give regional office location and claim number)*

List of enclosure in attachment

10. I DESIRE TO APPEAR BEFORE THE BOARD IN WASHINGTON, D.C. *(At no expense to the Government) (X one)* [X] YES. THE BOARD WILL DETERMINE IF WARRANTED. [ ] NO. CONSIDER MY APPLICATION BASED ON RECORDS AND EVIDENCE.

11.a. COUNSEL *(If any)* NAME *(Last, First, Middle Initial)* and ADDRESS *(Include ZIP Code)*	b. TELEPHONE *(Include Area Code)* (202) 454-2809 c. E-MAIL ADDRESS [redacted]com d. FAX NUMBER *(Include Area Code)* (202) 330-5610
[redacted]	e. I WOULD LIKE ALL CORRESPONDENCE/DOCUMENTS SENT TO ME ELECTRONICALLY. [X] YES [ ] NO

12. APPLICANT MUST SIGN IN ITEM 15 BELOW. If the record in question is that of a deceased or incompetent person, LEGAL PROOF OF DEATH OR INCOMPETENCY MUST ACCOMPANY THE APPLICATION. If the application is signed by other than the applicant, indicate the name *(print)* _____ **and relationship by marking one box below.**

[ ] SPOUSE [ ] WIDOW [ ] WIDOWER [ ] NEXT OF KIN [ ] LEGAL REPRESENTATIVE [ ] OTHER *(Specify)*

13.a. COMPLETE CURRENT ADDRESS *(Include ZIP Code)* OF APPLICANT OR PERSON IN ITEM 12 ABOVE *(Forward notification of all changes of address)*	b. TELEPHONE *(Include Area Code)* [redacted] c. E-MAIL ADDRESS [redacted] d. FAX NUMBER *(Include Area Code)* none
[redacted]	

14. I MAKE THE FOREGOING STATEMENTS, AS PART OF MY CLAIM, WITH FULL KNOWLEDGE OF THE PENALTIES INVOLVED FOR WILLFULLY MAKING A FALSE STATEMENT OR CLAIM. *(U.S. Code, Title 18, Sections 287 and 1001, provide that an individual shall be fined under this title or imprisoned not more than 5 years, or both)*

CASE NUMBER *(Do not write in this space)*

15. SIGNATURE *(Applicant must sign here)*	16. DATE SIGNED *(YYYYMMDD)*
[redacted] Digitally signed by [redacted] Date: 2018.06.08 14:24:38 -04'00'	20180608

APPLICATION FOR CORRECTION OF MILITARY RECORD UNDER THE PROVISIONS OF TITLE 10, U.S. CODE, SECTION 1552

(Please read Privacy Act Statement and instructions on back BEFORE completing this application.)

OMB No. 0704-0003
OMB approval expires Dec 31, 2017

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b. NAME (Print - Last, First, Middle Initial)	c. PRESENT OR LAST PAY GRADE	d. SERVICE NUMBER (If applicable)	e. SSN
Muhammad, James D	E-1	none	[redacted]

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Applicant was unjustly and excessively punished for refusal to accept Anthrax Vaccine.

Verbose discussion in attachment

a. IS THIS A REQUEST FOR RECONSIDERATION OF A PRIOR APPEAL?	YES / NO	b. IF YES, WHAT WAS THE DOCKET NUMBER?	c. DATE OF THE DECISION
		none	none

7. ORGANIZATION AND APPROXIMATE DATE *(YYYYMMDD)* **AT THE TIME THE ALLEGED ERROR OR INJUSTICE IN THE RECORD OCCURRED** *(Entry required)* 20030409 [redacted] BN [redacted], [redacted], Camp Lejeune, NC; 20070320 NAMALA

8. DISCOVERY OF ALLEGED ERROR OR INJUSTICE

a. DATE OF DISCOVERY (YYYYMMDD)	b. IF MORE THAN THREE YEARS SINCE THE ALLEGED ERROR OR INJUSTICE WAS DISCOVERED, STATE WHY THE BOARD SHOULD FIND IT IN THE INTEREST OF JUSTICE TO CONSIDER THE APPLICATION.
20180410	none

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List of enclosure in attachment

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11.a. COUNSEL (If any) NAME (Last, First, Middle Initial) and ADDRESS (Include ZIP Code)	b. TELEPHONE (Include Area Code) (202) 454-2809 c. E-MAIL ADDRESS mark@markzaid.com d. FAX NUMBER (Include Area Code) (202) 330-5610
Zaid, Mark S; 1250 Connecticut Avenue, N.W. Suite 700; Washington, D.C. 20036	

e. I WOULD LIKE ALL CORRESPONDENCE/DOCUMENTS SENT TO ME ELECTRONICALLY. — [X] YES [ ] NO

12. APPLICANT MUST SIGN IN ITEM 15 BELOW. If the record in question is that of a deceased or incompetent person, LEGAL PROOF OF DEATH OR INCOMPETENCY MUST ACCOMPANY THE APPLICATION. If the application is signed by other than the applicant, indicate the name *(print)* _____ **and relationship by marking one box below.**

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13.a. COMPLETE CURRENT ADDRESS (Include ZIP Code) OF APPLICANT OR PERSON IN ITEM 12 ABOVE (Forward notification of all changes of address.)	b. TELEPHONE (Include Area Code) [redacted] c. E-MAIL ADDRESS [redacted] d. FAX NUMBER (Include Area Code) none
[redacted]	

14. I MAKE THE FOREGOING STATEMENTS, AS PART OF MY CLAIM, WITH FULL KNOWLEDGE OF THE PENALTIES INVOLVED FOR WILLFULLY MAKING A FALSE STATEMENT OR CLAIM. (U.S. Code, Title 18, Sections 287 and 1001, provide that an individual shall be fined under this title or imprisoned not more than 5 years, or both.)	CASE NUMBER (Do not write in this space.)
15. SIGNATURE (Applicant must sign here.) [redacted]	16. DATE SIGNED (YYYYMMDD) [redacted]

PRIVACY ACT STATEMENT

AUTHORITY: 10 U.S.C. 1552 and E.O. 9397, as amended (SSN).

PRINCIPAL PURPOSE(S): To initiate an application for correction of military record. The form is used by Board members for review of pertinent information in making a determination of relief through correction of a military record. Completed forms are covered by correction of military records SORNs maintained by each of the Services or the Defense Finance and Accounting Service. The DoD Systems of Records Notices can be located at: http://dpclo.defense.gov/Privacy/SORNsIndex/DODComponentNotices.aspx.

ROUTINE USE(S): The DoD Blanket Routine Uses at http://dpclo.defense.gov/Privacy/SORNsIndex/BlanketRoutineUses.aspx may apply to this collection.

DISCLOSURE: Voluntary. However, failure by an applicant to provide the information not annotated as "optional" may result in a denial of your application. An applicant's SSN is used to retrieve these records and links to the member's official military personnel file and pay record.

Applicable SORNs:
Army (http://dpclo.defense.gov/Privacy/SORNsIndex/DODComponentArticleView/tabid/7489/Article/6000/a0015-185-sfmr.aspx)
Navy and Marine Corps (http://dpclo.defense.gov/Privacy/SORNsIndex/DODwideSORNArticleView/tabid/6797/Article/6510/nm01000-1.aspx)
Air Force (http://dpclo.defense.gov/Privacy/SORNsIndex/DODwideSORNArticleView/tabid/6797/Article/5904/f036-safpc-d.aspx)
Defense Finance and Accounting Service (http://privacy.defense.gov/notices/dfas/T5015a.shtml)
Coast Guard (http://www.gpo.gov/fdsys/pkg/FR-2011-10-28/html/2011-27881.htm)

Official Military Personnel Files:
Army (http://dpclo.defense.gov/Privacy/SORNsIndex/DODwideSORNArticleView/tabid/6797/Article/6131/a0600-8-104-ahrc.aspx)
Navy (http://dpclo.defense.gov/Privacy/SORNsIndex/DODwideSORNArticleView/tabid/6797/Article/6405/n01070-3.aspx)
Marine Corps (http://dpclo.defense.gov/Privacy/SORNsIndex/DODComponentArticleView/tabid/7489/Article/6775/m01070-6.aspx)
Air Force (http://dpclo.defense.gov/Privacy/SORNsIndex/DODwideSORNArticleView/tabid/6797/Article/5876/f036-af-pc-c.aspx)
Coast Guard (http://www.gpo.gov/fdsys/pkg/FR-2011-10-28/html/2011-27881.htm)

INSTRUCTIONS

Under Title 10 United States Code Section 1552, Active Duty and Reserve Component Service members, Coast Guard, former Service members, their lawful or legal representatives, spouses of former Service members on issues of Survivor Benefit Program (SBP) benefits, and civilian employees with respect to military records other than those related to civilian employment, who feel that they have suffered an injustice as a result of error or injustice in military records may apply to their respective Boards for Correction of Military Records (BCMR) for a correction of their military records. These Boards are the highest level appellate review authority in the military. The information collected is needed to provide the Boards the basic data needed to process and act on the request.

1. All information should be typed or printed. Complete all applicable items. If the item is not applicable, enter "None."

2. If space is insufficient on the front of the form, use the "Remarks" box below for additional information or attach an additional sheet.

3. List all attachments and enclosures in item 9. Do not send original documents. Send clear, legible copies. Send copies of military documents and orders related to your request, if you have them available. Do not assume that they are all in your military record.

4. The applicant must exhaust all administrative remedies, such as corrective procedures and appeals provided in regulations, before applying to the Board of Corrections.

5. ITEM 5. State the specific correction of record desired. If possible, identify exactly what document or information in your record you believe to be erroneous or unjust and indicate what correction you want made to the document or information.

6. ITEM 6. In order to justify correction of a military record, it is necessary for you to show to the satisfaction of the Board by the evidence that you supply, or it must otherwise satisfactorily appear in the record, that the alleged entry or omission in the record was in error or unjust. Evidence, in addition to documents, may include affidavits or signed testimony of witnesses, executed under oath, and a brief of arguments supporting the application. All evidence not already included in your record must be submitted by you. The respons bility of securing evidence rests with you.

7. ITEM 8. U.S. Code, Title 10, Section 1552b, provides that no correction may be made unless a request is made within three years after the discovery of the error or injustice, but that the Board may excuse failure to file within three years after discovery if it finds it to be in the interest of justice.

8. ITEM 10. Personal appearance before the Board by you and your witnesses or representation by counsel is not required to ensure full and impartial consideration of your application. If the Board determines that a personal appearance is warranted and grants approval, appearance and representation are permitted before the Board at no expense to the government.

9. ITEM 11. Various veterans and service organizations furnish counsel without charge. These organizations prefer that arrangements for representation be made through local posts or chapters.

10. ITEM 12. The person whose record correction is being requested must sign the application. If that person is deceased or incompetent to sign, the application may be signed by a spouse, widow, widower, next of kin (son, daughter, mother, father, brother, or sister), or a legal representative that has been given power of attorney. Other persons may be authorized to sign for the applicant. Proof of death, incompetency, or power of attorney must accompany the application. Former spouses may apply in cases of Survivor Benefit Plan (SBP) issues.

11. For detailed information on application and Board procedures, see: Army Regulation 15-185 and www.arba.army.pentagon.mil; Navy - SECNAVINST.5420.193 and www.hq.navy.mil/bcnr/bcnr.htm; Air Force Instruction 36-2603, Air Force Pamphlet 36-2607, and www.afpc.randolph.af.mil/safmrbr; Coast Guard - Code of Federal Regulations, Title 33, Part 52.

MAIL COMPLETED APPLICATIONS TO APPROPRIATE ADDRESS BELOW

ARMY	NAVY AND MARINE CORPS	AIR FORCE	COAST GUARD
Army Review Boards Agency 251 18th Street South, Suite 385 Arlington, VA 22202-3531	Board for Correction of Naval Records 701 S. Courthouse Road, Suite 1001 Arlington, VA 22204-2490	Board for Correction of Air Force Records SAF/MRBR 550-C Street West, Suite 40 Randolph AFB, TX 78150-4742	Department of Homeland Security Office of the General Counsel Board for Correction of Military Records 245 Murray Lane, Stop 0485 Washington, DC 20528-0485

17. REMARKS

Attachment of Explanation for Block 5 of DD form 149

1. Request upgrade of Discharge from Bad Conduct to honorable Discharge
    1a Update discharge code RE-1
    1b. Restoration of Last Rank to E5

2 Update Errors on DD214
    2a. Issue 2nd award Good Conduct Medal based upon qualifying time periods of service
    2b Update Box 11 DD214 to include missing MOS[redacted]
    2c Update Box 12A DD214 to correct date of entry as 19991129
    2d Update Box 15A to properly record "yes"
    2e Per request 1, update block 24 DD214 to Honorable
    2f Per request 1a update block 25 to RE-1
    2g Per request 1 update block 26 to code consistent with RE-1
    2h Per request 1a update block 28 to Honorable
    2i Consistent with request 2g redact entry in block 29 from record
    2j Adjust date of discharge to match date of approval of this application

3. Per request 1..Request expungement of DNA Sample data from all databases

4. Petitioner requests after favorable results of this board that a newly updated Fitness Report is written to reflect exemplary performance above my grade, training and education.

5. Petitioner requests that rank of Sergeant (E-5) is restored and updated on all applicable documents

6. After successful application, petitioner requests administrative recall to Active Duty for 1-day for award of Navy-Marine Corps Achievement Medal for sustained exemplary performance

7. Request a favorable letter forwarded to Veterans Affairs that merits award of equitable tolling for use of GI Bill & Marine Corps College Fund as annotated on Service Contract.

8. Petitioner requests that after successful resolution the board to determine that had it not been for matters pertaining to Anthrax Vaccine refusal, petitioner would have participated in a deployment with the Marine Expeditionary Brigade to Kuwait and then Iraq and a unit promotion (meritoriously) and in the interest of justice this board sees fit to administratively promote petitioner to rank of Staff Sergeant (E-6).

9. Petitioner requests BCNR to to locate all documentation that would ultimately be found as a result of any FOIA or other extraordinary requests and investigate the Meritorious Commissioning Program Selection Board results released approximately 30 Aug 2002 and return a finding that petitioner was in-fact originally selected for the program and it is highly likely that petitioner would have met graduation requirements for commissioning as an O-1E in the Naval Aviation Program and for the board to administratively award petitioner the grade of O-1E.

Attachment of Explanation for Block 6 of DD form 149

Timeline of events related to matters involving petitioner's core complaint

- 199609xx the Department of Defense contractor filed an application for license as an Investigational New Drug (IND) from Food and Drug Administration (FDA) to use Anthrax Vaccine Adsorbed (AVA) for protection of servicemembers against Anthrax in natural and weaponized forms[1]

- 19991129[2] Petitioner Entered Active Duty Service in USMC with qualifications at pay grade E-2
- 20000225 Petitioner Completed Recruit Training after 11 weeks as a Squad Leader
- 20000402 Petitioner was promoted to the rank of Lance Corporal, E-3 (Meritoriously) based on #1 class standing and leadership performance and potential
- 20000407 Petitioner graduated Marine Combat Training, School of Infantry as Company Honor Graduate out of 302; awarded Certificate of Commendation
- 20000616 Petitioner graduated [redacted] Twentynine Palms as Class Honor Graduate (GPA 99.0271) and a School Director's Award
- 200008xx Petitioner was assigned to Marine Corps Base, Camp Lejeune, II Marine Expeditionary Force, [redacted] as a [redacted] Marine
- Petitioner auditioned and was accepted as a member of the Battalion Color Guard
- 200102xx Petitioner was selected for the Fleet Assistance Program and assigned to Marine Corps Base, Camp Lejeune [redacted] as [redacted] NCOIC, outside of his Military Occupational Specialty while simultaneously taking college courses and continuing to serve in the [redacted] Color Guard, actions for which petitioner was awarded a subsequent Certificate of Commendation
- Petitioner was interviewed and came highly recommended to represent the [redacted] at a Battalion Level Board
- 20010801 Petitioner was Promoted to the rank of Corporal, E-4
- 200108xx Petitioner was transferred back to [redacted] to serve as a [redacted] Non-Commissioned Officer (NCO) and [redacted] Platoon Training NCO, Safety NCO and [redacted] Chief
- 20011019 Petitioner completed Sergeant's Distance Education Course[3]
- 200201xx Petitioner deployed in support of the Global War on Terrorism as a member of a 6-man detachment attached to [redacted] and was awarded a tertiary Certificate of Commendation
- 200203xx Petitioner returned to CONUS to resume garrison duties

[1] See 20031222 Doe v Rumsfeld enclosure
[2] See Service Contract
[3] See Completion Certificate

- 20020603 Petitioner appeared before a board convened by Commanding Officer, [redacted] where petitioner was recommended for acceptance into the Meritorious Commissioning Program and attendance at Officer Candidate School for commissioning as a 2nd Lieutenant, O-1 and follow-on accession in the Naval Aviation training pipeline[4]
- 20020620 Petitioner earned an Associate of Arts degree (with Honors) while attending classes during off-duty time (GPA 3.88)
- 20020723 Petitioner completed Corporal's Leadership Course with a ranking of #3 of 42; awarded a Meritorious Mast and a Marine Corps Association Certificate of Achievement
- 20020912 Petitioner was awarded a Tan Belt in the Marine Corps Martial Arts Program
- 20021101 Petitioner was Promoted to the rank of Sergeant, E-5 and assumed the additional training and billet as the [redacted] Company Nuclear, Biological and Chemical Decontamination Officer
- 20021201 Petitioner was awarded the Marine Corps Good Conduct Medal by Commanding Officer, [redacted]
- 20021212 Petitioner was ordered by Executive Officer, [redacted] Battalion to receive Anthrax Vaccination Immunization Program (AVIP) injection, which petitioner refused[5]
    - 20030318 Six plaintiffs, referred to a John Doe filed a request for injunction with the US District Court in the District of Columbia against Donald Rumsfeld, Secretary of Defense to prevent the defendant from ordering plaintiffs as servicemembers to submit to AVIP.
- [redacted] petitioners Official Military Personnel File is amended
- 20030409 absent controversy of knowledge of Doe v Rumsfeld, petitioner was convicted at Special Court Martial (SCM) convened by Commanding Officer, [redacted] Battalion of a single charge and specification of violation of Article 90, (Willful Disobedience of a Lawful Order) consistent with Guilty Plea absent requesting any special consideration and was awarded with a reduction in rank to E-1, confinement for 60-days and a Bad Conduct Discharge (BCD)
- 20030527 Petitioner released from confinement early due to exemplary conduct
    - 20031222 the US District Court determined "This Court is persuaded that AVA is an investigational drug and a drug being used for an unapproved purpose. As a result of this status, the DoD is in violation of 10 U.S.C. § 1107, Executive Order 13139, and DoD Directive 6200.2." and further, "Absent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs" and the further "ORDERED that the Motion for a Preliminary Injunction is GRANTED. In the absence of a presidential

[4] See MCP Board Recommendation
[5] Written Refusal included
[6] Court Order included

waiver, defendants are enjoined from inoculating service members without their consent."[7]

- DoD subsequently complied with the court and promulgated orders that Commanding Officers were to halt the execution of all AVIP actions
- 20031230 The FDA grants licensure of AVA pursuant to application filed by DoD; the court accordingly lifts the AVIP injunction
- 20040105 FDA issues ruling on the efficacy and safety of AVIP, granting the license to the Department of Defense that it sought in Sept 1996; the court accordingly lifts the AVIP injunction
- Doe Complainants reapply for injunction on the basis that FDA license was improperly granted, alleging the FDA violated the Administrative Procedures Act; the court granted Plaintiff's request for injunctive relief
- 20041027 the US District Court[8] concurred with Doe's complaint and stated, "Unless and until FDA follows the correct procedures to certify AVA as a safe and effective drug for its intended use, defendant DoD may no longer subject military personnel to involuntary anthrax vaccinations absent informed consent or Presidential waiver." and determined that "the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver".
- 20050405 DoD Under Secretary of Defense memorandum "Implementation of Resumption of the Anthrax Immunization Program (AVIP) Under Emergency Use Authorization (EUA)" was issued wherein it states, "You may refuse anthrax vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination."[9]
- 20050406 DoD sought relief that the injunction is modified to permit use of AVA under Emergency Use Authorization; the court granted the request
- 20051219 The FDA grants final approval and licensure of AVIP[10]
- 20060209 US Court of Appeals determined that an appeal of Doe V Rumsfeld is moot and stated, "By its own terms, then, the injunction has dissolved, and this case no longer presents a live controversy on which we may pass judgment."[11]

- 20060531 Petitioner's appeals to the United States Navy-Marine Corps Court of Criminal Appeals (NMCCA) without raising any issues of lawfulness of AVIP as

[7] See 20031222 Doe v Rumsfeld enclosure
[8] See 20041027 Doe v Rumsfeld
[9] See Implementation of AVIP under EUA
[10] 20050406 Doe v. Rumsfeld, 501 F. Supp. 2d 186, 188
(D.D.C. 2007)(discussing 70 Fed. Reg. 75180 (Dec. 19, 2005)).
[11] Opinion included

uncovered in Doe V Rumsfeld where NMCCA denied relief on the matters raised [12]

    - 20061012 Department of Defense resumes AVIP program[13] unencumbered
- 20070221 the US Court of Appeals of Armed Forces stated, "On consideration of the petition for grant of review...the decision of the (NMCCA) is affirmed."[14] The petitioner's judicial process was complete
    - 20070821 The court explained in an opinion awarding attorneys' fees to the Doe plaintiffs, "there is no question that the plaintiffs have prevailed overall as they achieved the permanent injunctive relief that they sought" and in another place, "The Court concludes that plaintiffs are entitled to fees and costs for litigating this action, including on appeal, because plaintiffs are the prevailing party and the government's position was not substantially justified."[15]
- Petitioner maintains that at present he is a productive citizen and that continued indefinite punitive status would be an injustice[16]

Other matters germane to this application

- Petitioner was originally designated MOS [redacted], the Marine Corps deprecated the [redacted] series Occupation Code in favor of [redacted] OCC where petitioner was designated [redacted] petitioner's DD-214 errantly omits MOS [redacted]
- Date of entry on DD-214 errantly fails to match actual date of entry and is administrative error[17]
- Petitioner's DD-214 as issued does not indicate GI Bill eligibility as recorded on Enlistment Contract and fulfilled during period of service by contribution of $100/month for 12 consecutive months[18]
- Petitioner contends that qualifying time for issuance of the Marine Corps Good Conduct medal (at minimum) begins on 20030410 (date after SCM) and ends at 20070221 (date of closure by CAAF) during a period where petitioner was subject to the Uniform Code of Military Justice and there is no adverse action in the record; petitioner is qualified for a subsequent award
    - Military courts and boards when adjudicating Anthrax issues have granted favorable relief but some dissenting members contend that a servicemember disobeys an Anthrax order at his own peril, despite that prior to 20051219 AVIP was statutorily unlawful. This places Petitioner in a "no-win" situation where case law has been established that demonstrates that orders do not have "inherent authority"

[12] Opinion included
[13] Deputy SecDEF Memo Included
[14] http://www.armfor.uscourts.gov/newcaaf/journal/2007/2007Feb htm
[15] Opinion included
[16] See included BCMR cases where relief was granted for other individuals
[17] Service Contract included
[18] See Leave and Earnings Statement

    - In support of the above, in Little vs Barreme[19], the US Supreme Court found that upon judicial analysis the Commander In Chief issued an illegal order that was executed by a Naval Commander (Little), which ought to have been curtailed
    - USAF BCMR BC-2006-01924[20] also supports petitioner's request for relief for same reasons as stated in the narrative
- Petitioner represents that if controversy surrounding AVIP would not have existed, petitioner very likely would have continued with his military career through retirement eligibility.
- Petitioner contends that his treatment was unjust and the most severe of any other servicemember due to disparities in treatment which ranged from no adverse action, verbal reprimands, letters of reprimand, Article 15 and Courts Martials[21] despite there being a Uniform Code of Military Justice system in place
- Petitioner is requesting that the board exercise lenient judgement in granting request to redact lost time noted on DD-214
- Petitioner requests that refusal to submit to Anthrax vaccination to no longer to be considered a Qualifying Military Offense and as such requests expungement of his DNA sample from all databases[22]
- Petitioner requests that the board relax any timeliness concerns due to the fact that some of the matters addressed were not discovered until as recent at 20180410 but all matters are inseparably linked and did not reach full fruition until such time and that it would be in the best interest of justice to fully weigh the application
- Petitioner represents that successful completion of a BCNR request qualifies as a meritorious event in a servicemember's career that warrants an award and that the appropriate award is the Navy and Marine Corps Achievement Medal
- Petitioner requests that the board see fit to award meritorious promotion to E-6 commensurate with other members of [redacted] Company, [redacted] that deployed while petitioner was removed from deployment roster for Anthrax refusal.
- Petitioner was administratively forwarded to HQMC but subsequently due to intra-unit miscommunication, Commander's recommendation was rescinded through an unofficial channel. The MCP selection board results were delayed while another candidate was selected in place of petitioner. Subsequently, the unit matter was cleared up with a finding that petitioner had zero culpability for the incident in question. The petitioner received this information as a result of a Request Mast but unfortunately by the time he was made aware of the cause it was presumed too late to petition HQMC to attend OCS because the class had convened. Petitioner requests this board return a finding of a high likelihood that petitioner would have been commissioned O-1E and to grant an administrative commission under Secretarial Authority and that equitable credit for time served as an enlisted Marine is credited toward waiver of US Code Title 10 requirements.

[19] Citation included
[20] AFBCMR BC-2006-01924 enclosed
[21] See article of Lt Col. Lacken
[22] Orders to submit to DNA collection included

Attachment of Explanation for Block 9 of DD form 149

1. Attachments for DD-149 Blocks 5, 6 & 9
2. DD-214
3. 20031222 Doe v Rumsfeld
4. Service Contract
5. Meritorious Commissioning Program Board Recommendation Letters and results (4)
6. Document of Refusal of AVIP order
7. [redacted]
8. 20041027 Doe v Rumsfeld
9. Memo: Implementation of AVIP under Emergency Use Authorization
10. 20050406 Doe v Rumsfeld
11. 20060209 Doe v Rumsfeld
12. Navy Marine Corps Court of Criminal Appeals Opinion
13. 20061012 AVIP Resumption policy letter
14. 20070821 Doe v Rumsfeld
15. BCNR 5448-14, BCNR 7959-05, Navy DRB_MD0900741 Navy DRB_ND0701006 and AFBCMR BC-2006-01924
16. LES May 2003
17. Citation, Little v Barreme
18. Stripes article- Re: Lt Col Lacken
19. NAMALA DNA Collection Order
20. Picture Collage
21. Biography
22. Professional Certificates
23. FAA Certificate Verification Letter
24. Kukkiwon Certificate
25. Letters of support (13)
26. Certificates (13) & Document showing Marine Corps Communication Electronics School Class ranking
27. SMART Transcript
28. Modified Deployment Roster
29. MCP inquiry email
30. MCP Selection Board Statistics

*Documents listed above are in the order in which they appear in the full application

DEPARTMENT OF THE NAVY
NAVY AND MARINE CORPS APPELLATE LEAVE ACTIVITY
716 SICARD STREET SE ROOM 46
WASHINGTON NAVY YARD DC 20374-5083

IN REPLY REFER TO
FEB 28 2007

SPECIAL COURT-MARTIAL SUPPLEMENTAL ORDER NO. [redacted]

In the special court-martial case of Sergeant James D. Muhammad, U.S. Marine Corps, [redacted], the approved sentence to confinement for 60 days, reduction to pay grade E-1, and a bad-conduct discharge, as promulgated in Commanding Officer, [redacted] Battalion, [redacted], Camp Lejeune, NC, Special Court-Martial Order No. [redacted], dated 22 September 2003, has been affirmed in NMCCA No. [redacted]. Article 71(c), UCMJ having been complied with, the bad-conduct discharge will be executed.

M. E. BROOKS
Commander, U.S. Navy
Commanding Officer

Distribution:
Original: Original Record of Trial
Duplicate Original: Service Record (1)
NAMALA WASHINGTON DC
DIR NAVCLEM&PARBD WASHINGTON DC 20374-5023 (1)
[redacted] CAMP LEJEUNE NC 28542 (2)
DFAS KANSAS CITY MO 64197 (1)
CO [redacted]
MJ (1), DC (1), TC (1)
Appellant (1)
DNA (1)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1, *et al*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-707 (EGS)
DONALD H. RUMSFELD, *et al*	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs, members of the active duty and selected National Guardsmen components of the Armed Forces as well as civilian contract employees of the Department of Defense ("DoD") who have submitted or have been instructed to submit to anthrax vaccinations without their consent pursuant to the Anthrax Vaccine Immunization Program ("AVIP"), commenced this action against the Secretary of Defense (Donald Rumsfeld), the Secretary of Health and Human Services (Tommy Thompson), and the Commissioner of the Food and Drug Administration (Mark McClellan).

Because plaintiffs maintain that Anthrax Vaccine Adsorbed ("AVA") is an experimental drug unlicensed for its present use and that the AVIP violates federal law (10 U.S.C. § 1107), a Presidential Executive Order (Executive Order 13139), and the

DoD's own regulations (DoD Directive 6200.2), plaintiffs ask that in the absence of a presidential waiver the Court enjoin the DoD from inoculating them without their informed consent. Plaintiffs allege three causes of action against defendants: (1) violation of the Administrative Procedure Act ("APA") by defendant DoD based on the DoD's failure to follow federal law, a presidential executive order, and DoD directive with respect to its AVIP; (2) violation of the APA by defendant DoD for its intent to inoculate plaintiffs with an unlicensed drug that is unapproved for its intended use; and (3) violation of the APA by the defendants' alteration of the licensed Federal Drug Administration ("FDA")-approved schedule of vaccination which rendered AVA a drug unapproved for its intended use.[1]

Defendants DoD and FDA maintain that the issues plaintiffs present are non-justiciable and that plaintiffs fail to present an evidentiary basis sufficient to support standing at the preliminary injunction stage. With respect to the merits, they allege that, in seeking to prevent the DoD from inoculating them, plaintiffs seek to undermine a key component of military readiness and defense against battlefield use of biological weapons.

Pending before this Court is a Motion for a Preliminary

[1] None of the plaintiffs alleged that their vaccination schedule was altered, so the Court does not reach the third cause of action.

Injunction. The central question before this Court is whether AVA is an "investigational" drug or a drug unapproved for its use against inhalation anthrax. Upon consideration of plaintiffs' motion for a preliminary injunction, the opposition, the reply, and oral arguments, as well as the statutory and case law governing the issues, and for the following reasons, it is, by the Court, hereby **ORDERED** that the Motion for a Preliminary Injunction is **GRANTED**. In the absence of a presidential waiver, defendants are enjoined from inoculating service members without their consent.

I. Background

A. Factual Background

In 1970, the National Institutes of Health ("NIH"), the agency then charged with licensing biologic drugs, *see* 37 Fed. Reg. 4004, 4004-04 (Feb. 25, 1972), licensed AVA for use against anthrax. *See* 36 Fed. Reg. 8704, 8705 (May 11, 1971). Two years later, authority to approve biologic drugs was delegated to the FDA. 37 Fed. Reg. 4004, 4004-05 (Feb. 25, 1972).

After the authority to license biologic drugs was delegated to the FDA, the agency initiated a review of the safety, effectiveness, and labeling of all licensed biologics. 21 C.F.R. 601.25. The Federal Register published a proposed rule containing the results of AVA's review on December 13, 1985. In

that product review, the independent Biologics Review Panel recommended that the vaccine be classified as safe, effective, and not misbranded. In their recommendations the panel discussed the Brachman study[2] and stated that the vaccine's "efficacy against inhalation anthrax is not well documented...no meaningful assessment of its value against inhalation anthrax is possible due to its low incidence." Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Reviews, 50 Fed Reg. 51,002 (Dec. 13, 1985)(to be codified at 21 C.F.R. pt. 610). To date the AVA label does not specify which method of anthrax exposure it protects against. The Proposed Rule published in the December 13, 1985, Federal Register has never been finalized.

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[2] According to the December 13, 1995, Federal Register:
The best evidence for the efficacy of anthrax vaccine comes from a placebo-controlled field trial conducted by Brachman covering four mills processing raw imported goat hair into garment interlining. The study involved approximately 1,200 mill employees of whom about 40 percent received the vaccine and the remainder received a placebo or nothing. The average yearly incidence of clinical anthrax in this population was 1 percent. During the evaluation period, 26 cases of anthrax occurred. Twenty-one had received no vaccines, four had incomplete immunization and one had complete immunization. Based on analysis of attack rates per 1,000 person-months, the vaccine was calculated to give 93 percent (lower 95 percent confidence limit = 65 percent) protection against cutaneous anthrax based on comparison with the control group. *Inhalation anthrax occurred too infrequently to assess the protective effect of vaccine against this form of the disease.* (emphasis added). Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Reviews, 50 Fed Reg. 51,002 (Dec. 13, 1985)(to be codified at 21 C.F.R. pt. 610).

On October 5, 1995, the U.S. Army Medical Research and Material Command wrote the Michigan Department of Public Health ("MDPH"), the vaccine's manufacturer, that they were enclosing a plan "to expand the indication for use to include projections from aerosol exposure to B. anthraces spores." Pls.' Compl. Ex. G, Letter from Anna Johnson-Winegar to Robert Myers of October 5, 1995. The plan specifically asserts that "[t]his vaccine is not licensed for aerosol exposure expected in a biological warfare environment." Pls.' Compl. Ex. G, Attachment to Letter from Anna Johnson-Winegar to Robert Myers of October 5, 1995. The plan proposed was to amend the anthrax vaccine license through an Investigational New Drug ("IND") application submission.

On October 20, 1995 (as reflected in a November 13, 1995, memorandum from the Department of the Army Joint Program Office for Biological Defense) a meeting was held to discuss modifying the anthrax vaccine license "to expand the indication to include protection against an aerosol challenge of spores."[3] Pls.' Compl. Ex. H, Mem. Regarding: Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet

[3] At this meeting, Colonel Arthur Friedlander, Chief of the Bacteriology Division of the U.S. Army Medical Research Institute for Infectious Diseases, briefed meeting participants on (1) evidence for a reduction in the number of doses of anthrax vaccine, (2) evidence for vaccine efficacy against an aerosol challenge, and (3) progress toward an in vitro correlate of immunity. SEALED.

Military Requirements from David L. Danley to Distribution List on November 13, 1995.

On July 2, 1996, the FDA held a meeting to consult with and provide guidance to the DoD and MDPH officials who were formulating the forthcoming September 1996 IND application. The Army "presented a plan in progress to develop correlates in immunity in animals and then in humans vaccinated with MAVA in order to obtain a specific indication for inhalation anthrax." Pls. Reply Ex. 1, Summary of the Michigan Anthrax Vaccine Adsorbed (MAVA) Pre-IND Meeting with the FDA: Specific Indication for Inhalation Anthrax; Change in Schedule and Route at ¶ 5.

In September 1996, AVA's manufacturer submitted an IND application to the FDA in an attempt to get FDA approval for a modification of the AVA license to demonstrate the drug's effectiveness against inhalation anthrax. The IND application is still pending and, to date, there is no indication for inhalation anthrax on the label or in the product insert.

In 1997, the Assistant Secretary of Defense "took...steps to confirm that AVA is approved for use against inhalation anthrax." Defs.' Opp'n at 10. For instance, the Assistant Secretary of Defense (Health Affairs) wrote to the FDA's Lead Deputy Commissioner, stating that the "DoD has long interpreted the scope of the license to include inhalation exposure, including that which would occur in a biological warfare context" and

inquiring "whether the FDA has any objection to our interpretation of the scope of the licensure for the anthrax vaccine." Defs. Opp'n. Ex. 3, Letter from Stephen Joseph to Mark Friedman of March 4, 1997. The Lead Deputy Commissioner responded "I believe your interpretation is not inconsistent with the current label." Defs. Opp'n. Ex. 2 Attach. 3, Letter from Mark Friedman to Stephen Joseph of March 13, 1997.

In a response to a citizen petition dated August 2002, the FDA's Associate Commissioner of Policy noted that the FDA still has yet to finalize the rule proposed in the December 13, 1985, Federal Register. But here, contradicting the panel's position regarding the Brachman study in the 1985 Federal Register, the FDA stated that the Brachman study included inhalation anthrax. Thus, the FDA concluded that "[t]he indication section of the labeling does not specify the route of exposure and thus includes both cutaneous and inhalation exposure." Pls.' Compl. Ex. D, Resp. to Citizen Pet. Dated October 12, 2001 from Margaret Dotzel to Russell Dingle on August 28, 2002.

The AVA product insert, which originally stated that the adverse reaction rate to the vaccine was 0.2 percent, was recently revised to reflect an adverse reaction rate between 5.0 percent and 35.0 percent. At least six deaths have been linked to the vaccine and the vaccine's pregnancy use risk has been upgraded from a Category C risk (risk cannot be ruled out) to a

Category D risk (positive evidence of risk.)

B. Legal Background

In 1998, in response to concerns about the use of investigational new drugs during the 1991 Gulf War that may have led to unexplained illnesses among veterans, Congress signed into law 10 U.S.C. § 1107. This provision prohibts the administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent. The consent requirement may be waived only by the President. In 1999, the President signed Executive Order 13139, pursuant to which the DoD must obtain informed consent from each individual member of the armed forces before administering investigational drugs and under which waivers of informed consent are granted only "when absolutely necessary." Exec. Order No. 13139, 64 Fed. Reg. 54,175 (September 30, 1999). In August, 2000, the DoD formally adopted these requirements in DoD Directive 6200.2.

In 1998, the DoD began a mass inoculation program using AVA as a preventative measure against inhalation anthrax for service members and civilian employees. The program was administered without informed consent or a presidential waiver. Plaintiffs contend that because AVA is not licensed for inhalation anthrax, its use by the DoD is not only investigational but it is also a drug unapproved for its intended use in violation of 10 U.S.C. §

1107, Executive Order 13139, and DoD Directive 6200.2. Tr. at 7-8. Defendants maintain that they are not in violation of any law because AVA is not an investigational new drug and it is licensed for inhalation anthrax.

II. Standard of Review

When seeking a preliminary injunction, the movant must demonstrate to the Court that: (1) there is a substantial likelihood that plaintiff will succeed on the merits; (2) plaintiff will be irreparably injured if an injunction is not granted; (3) an injunction will not substantially injure the other party; and (4) the public interest will be furthered by an injunction. *Davenport v. Int'l Bhd. of Teamsters*, 166 F.3d 356, 361 (D.C. Cir. 1999).

III. Discussion

A. Justiciability

1. Jurisdiction in an Article III Court

The parties in this case dispute whether the threshold requirement of justiciability is met. While plaintiffs maintain that the DoD's use of AVA in the AVIP is justiciable, defendants contend that the Article III case or controversy requirement is not met because (1) plaintiffs' claims are non-justiciable and (2) plaintiffs fail to present an evidentiary basis sufficient to

support standing for purposes of a request for preliminary injunction. Whether or not this Court can exercise jurisdiction over plaintiffs' claims depends on whether those claims fall within the narrow category of demands for equitable relief that are not barred under the D.C. Circuit's jurisprudence.

Courts have traditionally been hesitant to intervene in the conduct of military affairs. *See, e.g., United States v. Stanley,* 483 U.S. 669, 683-84 (1987); *Chappell v. Wallace,* 462 U.S. 296, 300 (1983). The general concern that courts are "ill-equipped to determine the impact upon discipline that any particular intrusion upon military authority might have," *Chappell,* 462 U.S. at 305, is heightened when courts are called upon to intervene between soldiers and their military superiors. *See, e.g. Gilligan v. Morgan,* 413 U.S. 1, 10 (1973) (observing that the "complex subtle, and professional decisions as to the composition, training, equipping, and control of a military force are essentially professional military judgments...."). Based on concerns surrounding judicial competence, the Supreme Court has declined to entertain service-related damages claims under the Federal Tort Claims Act, *see, e.g., Feres v. United States,* 340 U.S. 135 (1950), and *Bivens* actions "whenever the injury arises out of activity 'incident to service.'" *Stanley,* 483 U.S. at 681.

While claims for damages are nonjusticiable, the circuits

are divided with respect to the viability of claims for *injunctive relief* against the military. The case of *Speigner v. Alexander,* 248 F.3d 1292, 1296 (11th Cir. 2001), *cert denied,* 543 U.S. 1056 (2001), held that cases brought by enlisted personnel against the military for injuries incident to service are nonjusticiable, whether those claims request monetary or injunctive relief. In its decision, the Eleventh Circuit surveyed the appellate decisions addressing the justiciability of claims seeking injunctions against the military. The court noted that the Second, Fifth, Seventh, and Eighth Circuits had all found suits by enlisted personnel against the military for an injury incident to service nonjusticiable for injunctive relief as well as for damages. The *Speigner* court observed that the minority of circuits have held that injunctive relief is attainable against the military. The First Circuit, for instance, explicitly held that, "*Chappell* and *Stanley* make it clear that intramilitary suits alleging constitutional violations but not seeking damages are justiciable." *Wiggington v. Centracchio,* 205 F.3d 504, 512 (1st Cir. 2000). In *Jorden v. Nat'l Guard Bureau*, the Third Circuit held that "*Chappell* itself suggests that it leaves open claims for injunctive relief against the military." 799 F.2d 99, 100 (3d Cir. 1986).

The United States Court of Appeals for the D.C. Circuit, however, has not interpreted *Chappell* or *Feres* as embracing

categorical rules. In a recent opinion addressing the justiciability of a service member's suit for equitable relief the D.C. Circuit stated that the "Supreme Court has made clear...that *Feres* does not bar all suits by service personnel...." *Braanum v. Lake*, 311 F.3d 1127, 1130 (D.C. Cir. 2002). The *Braanum* court rejected any distinction between facial challenges and as applied challenges and noted that "some as applied challenges are plainly permitted." *Id.* The court found that Braanum's assertions that his due process and other rights were violated by the military taking actions against him in excess of its jurisdiction under the Military Code fell squarely within the Supreme Court's decision in *Schlesinger v. Councilman. See Braanum*, 311 F.3d at 1130 (citing 420 U.S. 738, 740 (1975)). In *Schlesinger*, the Court held that Article III courts had jurisdiction to entertain an Army captain's suit seeking an injunction against pending court martial proceedings based on conduct he claimed was non "service-related" and therefore outside the court martial jurisdiction. *Id.*

Plaintiffs in this case argue that district courts called upon to review military decisions must employ the test adopted in *Mindes v. Seamen*, 453 F.2d 197 (5th Cir. 1971), *affirmed on appeal after remand*, 501 F.2d 175 (5th Cir. 1974). *See* Pls.' Mot. at 5; Pls.' Reply at 7. The *Mindes* court held that a court should only review internal military affairs if there is an

allegation that a constitutional right has been deprived or an allegation that the military has acted in violation of applicable statutes or regulations. *Mindes*, 453 F.2d at 201. The Fifth Circuit determined that there are four factors a court must analyze:

> (1) the nature and strength of the plaintiff's challenge to the military determination;
> (2) the potential injury to the plaintiff if review is refused;
> (3) the type and degree of anticipated interference with the military function;
> (4) the extent to which the exercise of military expertise or discretion is involved (courts should defer to superior knowledge and experience of professionals in matters such as military personnel decisions or other areas that relate to specific military functions.)

Id.

While plaintiffs concede that the D.C. Circuit has not expressly adopted the *Mindes* test, they point out that it has not rejected the test in circumstances such as those presented in the case at bar. The case of *Kreis v. Secretary of the Air Force*, 866 F.2d 1508, 1512 (D.C. Cir. 1989), however, suggests to this Court that the D.C. Circuit Court may not look particularly favorably upon the *Mindes* analysis. In the *Kreis* case, an Air Force major brought suit seeking retroactive promotion or, in the alternative, correction of military records. The Court of Appeals held that the major's claim for retroactive promotion was a nonjusticiable military personnel decision and that his

alternative claims for correction of military records were justiciable. In holding that appellant's second claim was justiciable as a request for review of agency action, the court held that

> In dismissing this case, the district court considered neither *Chappell* nor our decisions relying upon it. Instead, the court concluded that appellant's entire complaint is nonjusticiable based solely on *Mindes*...which, the district court noted, we cited in *Dilley v. Alexander,* 603 F.2d 914, 920 (D.C. Cir. 1979). Our reference to *Mindes*, however, was not intended to foreclose judicial review of decisions involving the correction of military records; indeed, in the same paragraph, we said that the federal courts may inquire whether the Secretary's action in this area is "arbitrary, capricious, or contrary to the statutes and regulations governing that agency." *Id.* Nor did we adopt the *Mindes* court's four factor analysis, which, as the Third Circuit has pointed out, erroneously "intertwines the concept of justiciability with the standards to be applied to the merits of the case." *Dillard v. Brown,* 652 F.2d 316, 323 (3d Cir. 1981).

Kreis, 866 F.2d at 1512.

As the above discussion highlights, there is no bright line rule in the D.C. Circuit when it comes to establishing justiciability. What can be said with certainty is that this Circuit has not ruled out the right of individuals to seek injunctive relief against the military in civilian courts in all cases. Therefore, to assess the question of justiciability, this Court examines: (1) whether a court martial was pending against any of the plaintiffs, *see, e.g., Schlesinger,* 420 U.S. 738; (2) the degree to which a ruling by this Court would interfere with

supervisory-subordinate relationships on the battlefield and/or personnel decisions, see, e.g., *Chappell*, 462 U.S. 296; and (3) the extent to which action by this Court would affect or disrupt the goals of discipline, obedience, and uniformity, see, e.g., *Goldman v. Weinberger*, 475 U.S. 503 (1986).

First, this lawsuit was not instigated in an attempt to thwart a pending court martial, as was the case in *Schlesinger*, 420 U.S. 738. Moreover, this Court has no reason to believe that any of the plaintiffs are currently facing a court martial. In fact, three of the plaintiffs have complied with the order to take the inoculation and are seeking review of the DoD's order in this Court. Tr. at 38. Further, two of the plaintiffs are civilian employees and could not be subjected to court martial proceedings. Tr. at 36. At most, only one plaintiff could potentially be facing a court martial and, in the event that the situation arose, the case could be permitted to proceed with regard to the other plaintiffs. Thus, there are no concerns that this lawsuit was an attempt to interfere with pending court martial proceedings or that a judgment in this case will interfere with a pending court martial against one of the plaintiffs.

Second, plaintiffs allege that the DoD acted arbitrarily and capriciously by failing to adhere to statutes and regulations governing its activities. Their claim is against the Secretary

of Defense about a decision made in headquarters, not about a tactical decision military supervisors made in the field. Tr. at 13. Similarly, because plaintiffs are a diverse class and include civilian individuals who are not in the employ of the military, the danger of disrupting discipline and/or supervisory-subordinate relationships is minimal at best. Thus, a judgment in this Court would not interfere with a supervisory-subordinate relationship on the battlefield.

Third, while the Court is cognizant of the fact that allowing some service members to refuse inoculations at this stage could threaten the uniformity of the military, this case is not analogous to *Goldman*, where plaintiff sued to enjoin application of an Air Force regulation that forbade officers from wearing a yarmulke while on duty. *Goldman*, 475 U.S. 503. In *Goldman*, the Court recognized that importance of the appearance of uniformity for a effective functioning military. *Id.* at 510 ("The Air Force has drawn the line essentially between religious apparel that is visible and that which is not, and we hold that those portions of the regulations challenged here reasonably and evenhandedly regulate dress in the interest of the military's perceived need for uniformity.") Rather, here there will be no visible differences between persons who choose to receive the vaccine and those who choose not to receive the vaccine. Thus, concerns about uniformity diminish and a judgment in this case

would not affect the uniformity of military personnel to any substantial degree.

2. Availability of APA Review

Defendants maintain that Section 10 of the APA precludes judicial review. Defs.' Opp'n at 20. Specifically, they point to 5 U.S.C. § 701(b)(1)(G), which renders the APA's judicial review provisions inapplicable to acts of "military authority exercised in the field in time of war or in occupied territory." In addition, they refer to 5 U.S.C. § 701(b)(1)(F), a provision barring judicial review of "court martial and military commissions." Finally, defendants aver that the APA "excludes from its waiver of immunity...claims for which an adequate remedy is available elsewhere." *Transhio Sav. Bank v. Director OTS,* 967 F.2d 598, 607 (D.C. Cir. 1992).

The Court finds 5 U.S.C. § 701(b)(1)(G) inapplicable to the present situation. As plaintiffs note, the AVIP was announced in December, 1997, implemented initially in March, 1998, and implemented force-wide in May of that year. Due to the vaccine shortages discussed above, few of the service members who fought in Afghanistan in 2001-2003 were vaccinated at all. The recommencement of the AVIP program was announced on June 29, 2002, – a date which predated Congressional authorization for the

use of force in Iraq by four months and the recent hostilities by almost eighteen months. The plaintiffs in the instant case are not challenging military authority exercised in the field in a time of war or in occupied territory. In fact, according to plaintiffs, "[n]one of the plaintiffs are presently in the 'field' or in 'occupied territory.'" Pls.' Reply at 9. Moreover, the order for the program at issue in this case was given by the Secretary of Defense, not by commanders in the field. Similarly, the Court finds 5 U.S.C. § 551(1)(F) inapplicable, as none of the plaintiffs in this case have asked this Court to review a court martial or military commission proceedings.

Finally, defendants submit that the proper forum for plaintiffs to raise their claims is in the military justice system *after* having refused orders to take the vaccine. They cite the case of *New v. Cohen*, 129 F.3d 639 (D.C. Cir. 1997), as the principal authority in support of their proposition. While this D.C. Circuit opinion does embrace comity principles and the exhaustion requirement, it explicitly states that, at the heart of the comity principle "is the general rule that a federal court must await the final outcome of court-martial proceedings in the military justice system before entertaining an action by a service member *who is the subject of the court-martial*." *New*, 129 F.3d at 642. (emphasis added.) Similarly, the decision

refers repeatedly to "pending" court martial proceedings, service members "charged" with crimes by military authorities, and the prohibition on "collateral review" of court-martials. *Id.* at 643. The language in *New* strongly suggests that its holding applies to cases in which alternative channels within the military justice system are already being pursued by, or against, the plaintiffs. The thrust of the *New* decision is clearly that Article III courts should not interfere with the proceedings of military tribunals. In the present case, the Court has no reason to believe that any of the plaintiffs are currently facing a court martial. Moreover, the civilian plaintiffs cannot be subjected to court martial proceedings. Thus, the Court finds no reason to stay its hand based on *New*.

Instead, this Court reads *New* for the proposition that the courts are another option for plaintiffs. As *New* stated:

> [u]pon receiving orders which he thought to be illegal, New had two options. He could have chosen to obey the orders and then sought judicial review of the military's policies. *Cf. Goldman v. Weinberger,* 475 U.S. 503 (1986) (suit to enjoin application of Air Force regulation that forbade officer from wearing yarmulke while on duty and in uniform). Or he could follow the path that he took: disobey the orders and challenge their validity in the subsequent disciplinary proceedings.

New, 129 F.3d at 647. At oral argument plaintiffs' counsel informed this Court that all six of the plaintiffs have been ordered to submit to the vaccine. Tr. at 38. Three of the

plaintiffs obeyed the order and now seek judicial review. *Id.* This Court finds that it is one of the proper forums for this claim.

3. Standing

A core element of Article III's case or controversy requirement is that a plaintiff must establish that he or she has standing to sue. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). The "question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues." *Allen v. Wright*, 486 U.S. 737, 750-51 (1984). A plaintiff must meet three requirements in order to establish Article III standing. *See, e.g., Friends of Earth, Inc. v. Laidlaw Environmental Serv. (TOC), Inc.*, 528 U.S. 167, 180-91 (2000). First, she must demonstrate "injury in fact" – a harm that is "concrete," "actual or imminent, not conjectural or hypothetical." *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990); *see also City of Los Angeles v. Lyons*, 461 U.S. 95, 101 (1983). Second, she must establish causation – a "fairly...trace(able) connection between the alleged injury in fact and the alleged conduct of the defendant." *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41 (1976). Third, she must demonstrate redressability – a "substantial likelihood" that the requested

relief will remedy the alleged injury in fact. *Id.* at 45.

A plaintiff seeking injunctive relief demonstrates the first two standing requirements only by showing that the defendant is likely to injure the plaintiff. *Cone Corp. v. Florida Dep't of Transportation,* 921 F.2d 1190, 1205 (11th Cir. 1991). "Mere allegations will not support standing at the preliminary injunction stage." *Doe v. Nat'l Bd. Med. Exam'rs,* 199 F.3d 146, 152 (3rd Cir. 1999); *see also Nat'l Wildlife Fed. v. Burford,* 878 F.2d 422, 423 (D.C. Cir. 1989) *rev'd on other grounds sub non Lujan,* 497 U.S. 871 (burden of establishing standing at preliminary injunction stage is no less than for summary judgment).

In the present case, the government alleges that plaintiffs' claims of injury are purely speculative because adverse personnel actions against them for refusing inoculations may or may not occur. However, the Court agrees with plaintiffs that the defendants' argument ignores the fact that when challenging an investigational drug under 10 U.S.C. § 1107 an inoculation without informed consent or a presidential waiver is the injury. Tr. at 32. Because all six plaintiffs have been ordered to appear for the inoculation, and three of the six have already begun the series with more inoculations to follow, all plaintiffs have established that they will imminently suffer a harm that is actual, concrete, and inflicted at the hands of defendants unless

defendants are required to conform to 10 U.S.C. § 1107.

II. Likelihood of Success on the Merits

Having found that this claim is justiciable, the central question before the Court is whether AVA is being used as an investigational new drug or as a drug unapproved for its intended use. At bottom, this inquiry turns on whether the FDA has made a final decision on the investigational status of AVA; and if not (1) whether the 1996 IND application establishes the vaccine's status as an investigational drug and (2) whether the DoD is using AVA in a manner inconsistent with its license and intended use.[4]

As indicated previously, defendants' position is that 10 U.S.C. § 1107 is inapplicable because the AVA's license covers use against inhalation anthrax. Defs.' Opp'n Ex. 1, Goodman Decl. ¶ 11. They argue that the FDA has interpreted the lack of specificity concerning inhalation anthrax as permitting use of the vaccine against any route of exposure. While neither explaining the panel's finding in the December 15, 1985, Federal Register proposed rule stating that cases of inhalation anthrax

[4] In light of the fact that, as defendants concede, a vaccine can be licensed for one purpose and investigational for another, plaintiffs are correct in asserting that whether or not the vaccine in question is "licensed" is not, in itself, dispositive.

in the Brachman study were too infrequent to assess the vaccine against inhalation anthrax nor citing any additional studies of inhalation anthrax, defendants aver that agency officials have always considered the vaccine to include inhalation anthrax. Tr. at 92. They further allege that the 1996 IND application was submitted as a result of a dispute between underlings (Tr. at 92-93) and state that while the application is still technically pending, it is not longer being actively pursued. Tr. at 119. In addition, defendants point to a 1997 letter written by the Assistant Secretary of Defense stating that the IND application in no way suggests an official position that the DoD believed the approved label did not already encompass inhalation exposure. *See* Defs.' Opp'n at 31. Defendants note that such interpretations by an agency within its area of expertise are entitled to substantial deference. In support of their position, they cite several cases, including *Thomas Jefferson Univ. v. Shalala*, 513 U.S. 504, 512 (1994) and *Trinity Board of Fla., Inc. v. FCC*, 211 F.3d 618, 625 (D.C. Cir. 2000), standing for the proposition that an agency is entitled to deference with respect to the interpretation of the statutes it is tasked with administering.

While defendants' arguments concerning deference are correct, the dispute in this case has not focused on the language of a particular *DoD* statute. Rather, it is the *FDA's* term

"investigational" that is at the heart of the dispute. Title 10 U.S.C. § 1107 and the attendant DoD regulation apply only if the *FDA* determines that AVA is an investigational drug or a drug unapproved for its present purpose. As plaintiffs note, the letters and declarations defendants cite are not "formal FDA opinion(s)." *See* 21 C.F.R. § 10.85(k)(2000). Under 21 C.F.R. § 10.85(k)

> A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this Section. A statement or advice given by an FDA employee orally or given in writing but not under this section or § 10.90 is an informal communication that represents the best judgment of that employee at the time, but does not constitute an advisory opinion, does not bind or otherwise obligate or commit the agency to the views expressed.

Similarly, the personal opinions of FDA officials as expressed in a series of letters are not entitled to any particular deference. *See Christensen, et al v. Harris County, et al.*, 529 U.S. 576 (2000) (holding that an agency statutory interpretations contained in opinion letters are entitled to respect but only to the extent that interpretations have power to persuade.) The apparent change in position from the December 1985 proposed rule and the cryptic use of a double negative (i.e. "it is not inconsistent"), fail to persuade this Court that the view expressed in the 1997 letter is the FDA's formal opinion. Given that finding, the FDA has failed to provide any formal opinion *vis a vis* AVA's investigational status and the Court must

consider plaintiffs' arguments.[5]

In 1996, the manufacturer of the AVA, the Michigan Department of Public Health, filed an Investigational New Drug Application that remains open today. The manufacturer's stated purpose for filing the application was "to conduct clinical investigations designed to investigate changes in the approved labeling for the licensed product. The potential labeling would affect the specific clinical indication, route and vaccination schedule for AVA." Pls.' Compl. Ex. J, Letter from MDPH to Dr. Kathryn C. Zoon of October 20, 1996. The Introductory Statement to the 1996 IND application similarly provided that "[t]he ultimate purpose of this IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule." Pls.' Compl. Ex. K, Introductory Statement to the 1996 IND Application of September 20, 1996.

The source of the dispute concerns whether current use of the AVA for inhalation anthrax is licensed in light of the drug's present status and the IND application. Plaintiffs contend that,

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[5] At the oral argument, the government argued that the Citizen Petition states that the drug is licensed for inhalation anthrax and that is the agency's official position. Tr. at 86. However, the Court is persuaded by plaintiffs' arguments that the Citizen Petition addressed the licensing issue by merely relying on the 1997 Friedman letter and did not do the in-depth analysis as would be appropriate to make that kind of a determination or to contradict the opinion it expressed concerning the Bachman study in the 1985 Federal Register. *See* Tr. at 125.

as there has been insufficient study of the vaccine, its license does not incorporate inhalation anthrax. They rely on a 1985 panel that found that the license for anthrax was not broad enough to include inhalation anthrax. The panel findings were based partially on the Brachman Study, which noted that there were too few cases of inhalation anthrax to determine the efficacy of the vaccine. *See* Brachman and Friedlander, Vaccines 736 (eds. Plotkin and Mortimer)(1999). The Brachman Study observed that there have been "no controlled clinical trials in humans of the efficacy of the currently licensed U.S. vaccine." *Id.*[6] Plaintiffs correctly note that there have been no subsequent human studies on the efficacy of the vaccine against inhalation anthrax since that time. In addition, plaintiffs submit that defendants' own documents support their position that a vaccine is investigational if it is used in a manner, or for a purpose, identical to that set forth in the IND application. In this regard, plaintiffs cite a number of documents, including the October 5, 1995, letter by the U.S. Army Medical Research and Material Command, the November 13, 1995, memorandum from the Department of the Army's Joint Program Office for Biological Defense, and information provided by the Army at the July 2, 1996, FDA-sponsored meeting, chronicling the government's

[6] *See* Pls.' Reply at 13 n. 12 for relevant congressional testimony.

statements that the AVA lacked licensure for protection against inhalation anthrax.

Plaintiffs conclude that, because there is insufficient scientific evidence demonstrating that the anthrax vaccine protects against anthrax inhalation exposure, the government's claims violate fundamental precepts of drug law. Specifically, plaintiffs submit that the government claim violates 21 C.F.R. § 201.56(c), detailing general requirements on content and format of labeling for prescription drugs, which provides:

> The labeling shall be based whenever possible on data derived from human experience. No implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans shall be identified as such and included with human data in the appropriate section of the labeling, headings for which are listed in paragraph (d) of this section.

Moreover, plaintiffs contend that 21 C.F.R. § 201.57 (c)(2) is violated. That section provides that "All indications shall be supported by substantial evidence of effectiveness based on adequate and well-controlled studies." *Id.* Plaintiffs assert that the government cannot identify "substantial evidence of effectiveness based on adequate and well-controlled studies" for the anthrax vaccine with respect to protection against inhalation anthrax.

While the issues presented to the Court are complex, and the

evidence somewhat contradictory, the Court is ultimately persuaded that plaintiffs enjoy a substantial likelihood of success on the merits for the following reasons. The FDA, the only agency that this Court could properly defer to in determining AVA's status as an investigational drug, has failed to provide a formal opinion as to AVA's investigational status. Having made that determination, the Court is required to make its own inquiry and determination regarding AVA's investigational status. The Court looked at the labeling requirement, 21 C.F.R. § 201.56, which mandates that "[n]o implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." In the case of AVA, the 1985 panel found insufficient data to license the drug for use against inhalation anthrax. To date, no additional studies have been performed and AVA's label does not specify use of the vaccine for this purpose. Moreover, the Court is persuaded that the 1996 IND application remains pending today. The introduction to the application expressly states that one objective of the application is to obtain a specific indication for use of AVA against inhalation anthrax. While the government states that the inhalation anthrax aspect of the IND is no longer active, the documents submitted to this Court under seal suggest otherwise.[7] Finally, statements made by DoD officials suggest

[7] SEALED.

that the agency itself has, at some point at least, considered AVA experimental with respect to inhalation anthrax. Given all these factors, the Court would be remiss to conclude that the original license included inhalation anthrax. Having reached that conclusion, the DoD's administration of the inoculation without consent of those vaccinated amounts to arbitrary action.

III. The Public Interest

Plaintiffs maintain that Executive Order 13139, Department of Defense Directive 6200.2, and especially 10 U.S.C. § 1107, were enacted to protect soldiers from involuntarily serving as "guinea pigs" in a mass use of investigational medicine. Pls.' Mot. at 23. In their view, defendants' disregard of the violations has already caused half a million members of the armed forces to be experimental subjects without their consent.

Defendants base their public policy argument on the idea that requiring compliance with informed consent would render it infeasible to continue the AVIP for current military operations in Iraq or in conjunction with the war on terrorism. Essentially, defendants argue that the harm to the public interest would include disrupting the smooth functioning of the military, hampering military readiness, and reducing the military's ability to protect its service members. Should those individuals who have refused anthrax vaccinations be injured by

anthrax, their injuries or deaths would have a detrimental effect on the military and its operation at large. Defs.' Opp'n at 37. Plaintiffs counter by observing that if the risks of anthrax injuries were so manifestly present, the State Department, as well as the coalition forces of Britain and Australia, would have taken similar steps to protect their employees. Plaintiffs refute the government's argument concerning the cumbersome administrative results that could ensue from the granting of a preliminary injunction by stating that the DoD was able to comply with similar administrative proceedings in only three weeks between adoption of the predecessor of 10 U.S.C. § 1107 and the start of the Gulf War in 1991. Plaintiffs conclude by remarking that "if the danger articulated by the government is so clear...there should be little difficulty in convincing the President...to sign off on the required paperwork to make the AVIP mandatory...which is all plaintiffs can ask." Pls.' Reply at 24.

The Court is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate. Moreover, the Court is not convinced that requiring the DoD to obtain informed consent will interfere with the smooth functioning of the military. However, if obtaining

informed consent were to significantly interfere with military function, defendants are free to seek a presidential waiver. If the Executive branch determines that this is truly an exigent situation, then obtaining a presidential waiver would be an expeditious end to this controversy.

IV. Irreparable Harm

Plaintiffs argue that their injuries from non-consensual inoculations would be irreparable. They note that the informed consent documents provided to civilians as a result of the anthrax laden letters in the Fall of 2001 identify side effects such as Guillain-Barre Syndrome, multiple sclerosis, angiodema, aseptic meningitis, severe injection site inflammation, diabetes, and systemic lupus erythmatosis. In addition, the pregnancy risk assessment has, as noted above, been recently upgraded. Pls.' Mot. at 15. It is impossible to tell with any certainty what the long-term effects of the vaccination will be. Regardless, plaintiffs submit that no monetary award can adequately compensate individuals whose right to informed consent has been violated.

Defendants' position is that harm in the form of potential side effects is "hypothetical or, at best, unlikely to occur." Defs.' Opp'n at 40. Defendants refer to a *de minimis* risk of serious adverse reactions and report 105 serious adverse

reactions from AVA in over 830,000 recipients. *Id.* They stress that AVA has been used effectively in civilian industry for over 30 years.

Having found that AVA is an investigational drug under 10 U.S.C. § 1107, the Court is persuaded that requiring a person to submit to an inoculation without informed consent or the presidential waiver is an irreparable harm for which there is no monetary relief.

Conclusion

The Court has considered Plaintiff's Motion for a Preliminary Injunction, the Response and Reply thereto, counsel's representations at oral argument, and the relevant statutory and case law. In sum, because the record is devoid of an FDA decision on the investigational status of AVA, this Court must determine AVA's status for itself. This Court is persuaded that AVA is an investigational drug and a drug being used for an unapproved purpose. As a result of this status, the DoD is in violation of 10 U.S.C. § 1107, Executive Order 13139, and DoD Directive 6200.2. Thus, because the plaintiffs are likely to prevail on the merits, defendants will not face substantial harm by the imposition of an injunction, the public interest is served, and plaintiffs face irreparable harm, the Court finds that the plaintiffs meet the requirements for a Preliminary Injunction.

The women and men of our armed forces put their lives on the line every day to preserve and safeguard the freedoms that all Americans cherish and enjoy. Absent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs.

An appropriate Order accompanies this Opinion.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1, *et al*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-707 (EGS)
DONALD H. RUMSFELD, *et al*	)	
Defendants.	)	

ORDER

Pursuant to Fed. R. Civ. P. 65 and for the reasons stated by the Court in its Memorandum Opinion docketed this same day, it is this 22nd day of December, 2003, hereby

ORDERED that the Motion for a Preliminary Injunction is **GRANTED.** In the absence of a presidential waiver, defendants are enjoined from inoculating service members without their consent; and it is

FURTHER ORDERED that defendants are directed to file responsive pleadings by January 30, 2004; and it is

FURTHER ORDERED that an Initial Scheduling Conference is scheduled for **March 9, 2004 at 10:00 a.m.** Pursuant to LCvR 16.3 of the Local Rules and Fed. R. Civ. P. 26(f) counsel shall meet and confer by no later than February 24, 2004 and submit their Report addressing all topics listed in LCvR 16.3(c) by no later than March 2, 2004.

Signed: Emmet G. Sullivan
United States District Judge
December 22, 2003

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1, *et al*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-707 (EGS)
DONALD H. RUMSFELD, *et al*	)	
Defendants.	)	

ORDER

Pursuant to Federal Rule of Civil Procedure 58 and for the reasons stated by the Court in its Memorandum Opinion docketed this same day, it is this 27th day of October, 2004, hereby

ORDERED that the Plaintiffs' Motion for Summary Judgment is **GRANTED**. The FDA's Final Rule and Order is vacated and shall be remanded to the agency for reconsideration in accordance with the Court's Opinion and Order. Unless and until FDA classifies AVA as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. § 1107. Accordingly, the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver; and it is further

ORDERED that the Defendants' Motion for Summary Judgment is **DENIED.**

Signed: Emmet G. Sullivan
United States District Judge
October 27, 2004

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1, *et al*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-707 (EGS)
DONALD H. RUMSFELD, *et al*	)	
Defendants.	)	

MEMORANDUM OPINION

I. Introduction

Six plaintiffs, known as John and Jane Doe #1 through #6, bring this action to challenge the lawfulness of the government's Anthrax Vaccination Immunization Program ("AVIP"). Specifically, plaintiffs, who are members of the active duty or National Guardsmen components of the Armed Forces and civilian contract employees of the Department of Defense ("DoD") who have submitted or have been instructed to submit to anthrax vaccinations without their consent pursuant to AVIP, have filed a Motion for Summary Judgment challenging the Food & Drug Administration's ("FDA") determination that anthrax vaccine adsorbed ("AVA") is licensed for the purposes of combating inhalation anthrax (also known as aerosolized or weaponized anthrax). Defendants, the Secretary of Defense (Donald Rumsfeld), the Secretary of Health and Human Services (Tommy Thompson), and the Commissioner of the Food and

Drug Administration (Mark McClellan) have filed a Cross Motion for Summary Judgment asking this Court to declare that FDA's Final Rule and Order determining that AVA is licensed for anthrax regardless of the route of exposure is not arbitrary and capricious.

In 1997, the Department of Defense ("DoD") instituted AVIP and began inoculating service members with AVA to prevent the harmful effects caused by exposure to anthrax.[1] Compl. ¶ 33. Anthrax is an acute bacterial disease caused by infection with spores of *Bacillus anthracis,* which can enter the body in three ways: by skin contact (cutaneous), by ingestion (gastrointestinal), and by breathing (inhalation). *See* 50 Fed. Reg. at 51,058.

The AVIP is a multi-service vaccination program for active duty, Reserve and National Guard service members. Compl. ¶ 33. Under AVIP, military personnel are ordered to submit to a series of AVA inoculations over the course of eighteen months, followed by an annual booster vaccine. Compl. ¶ 47. If military personnel refuse to submit to the AVA inoculations, plaintiffs claim that they will be subject to military disciplinary actions, including court-martial convictions, forfeitures of pay, incarceration and other sanctions. Compl. ¶ 35. Civilian

[1] For manufacturing-related reasons, the vaccine program was reduced and later suspended beginning in July 2000. DoD formally resumed the program in June 2002.

plaintiffs who refuse to comply with AVIP are subject to dismissal as DoD employees or defense contractors. *Id.*

II. Statutory & Regulatory Framework

A. The Public Health Service Act & The Food, Drug, and Cosmetic Act

The Public Health Service Act ("PHSA"), 42 U.S.C. §§ 201 *et seq.*, and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, govern the regulation of biological products in the United States. The FDCA charges FDA with approving drugs, including vaccines, that are safe, effective, and not misbranded. 21 U.S.C. § 355(d). The PHSA grants FDA authority to issue licenses for products that are "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I).

Prior to 1972, the National Institute of Health ("NIH") was charged with implementing the PHSA's licensing requirement. In 1972, this authority was transferred to FDA. *See* Statement of Organization, Functions, and Delegations of Authority, 37 Fed. Reg. 12,865 (June 19, 1972). Upon the transfer of responsibility, FDA promulgated regulations establishing procedures for reviewing the safety, effectiveness, and labeling of all biological products previously licensed by the NIH. *See* Procedures for Review of Safety, Effectiveness and Labeling, 37 Fed. Reg. at 16,679. These regulations are codified in 21 C.F.R.

§ 601.25.

B. 21 C.F.R. § 601.25

21 C.F.R. § 601.25 established a two-stage process for reviewing biological products licensed prior to July 1, 1972. It directs FDA's Commissioner ("Commissioner") to appoint an advisory panel (1) to evaluate the safety and effectiveness of the previously licensed product, (2) to review the labeling of the product, and (3) to advise the Commissioner "on which of the biological products under review are safe, effective, and not misbranded." *See* 21 C.F.R. § 601.25(a).

Each panel must submit a report. *See* § 601.25(e). The report must contain a "statement . . . designat[ing] those biological products determined by the panel to be safe and effective and not misbranded" and this statement "may include any conditions relating to active components, labeling, tests required prior to release of lots, product standard, or other conditions necessary or appropriate for their safety and effectiveness." § 601.25(e)(1).

After reviewing the recommendation, the Commissioner must publish the panel report and a proposed order. *See* 21 C.F.R. § 601.25(f). After reviewing comments on the proposed order, the Commissioner "shall publish . . . a final order on the matters covered" therein, which shall "constitute final agency action

from which appeal lies to the courts." *See* §§ 601.25(g), 601.25(i).

C. Expert Panel Review

In 1973, FDA announced the Section 601.25 safety and effectiveness review of several "bacterial vaccine[s]" previously licensed under PHSA, including AVA, and solicited relevant data and information from manufacturers in order to determine whether the drugs were "safe, effective, and not misbranded." *See* Safety, Effectiveness and Labeling Review; Request for Data Information, 38 Fed. Reg. 5,358 (Feb. 28, 1973).

A scientific Advisory Panel was convened, and in 1980, after considering the relevant data and information, the Panel submitted its report. *See* A.R. 1-600. The Panel observed that AVA "appears to offer significant protection against cutaneous anthrax." The Panel noted that "there is sufficient evidence to conclude that anthrax vaccine is safe and effective under the limited circumstances for which [it] is employed." *See* A.R. at 338, 342. Therefore, the Report recommended that AVA "be placed in Category I" (safe, effective, and not misbranded) and that the appropriate licenses be continued because there is substantial evidence of safety and effectiveness for this product." *Id.* at 342. In the Panel's review of "recommended use," it found that "this product is intended solely for immunization of high-risk of

exposure industrial populations such as individuals who contact imported animal hides, furs, bone meal, wool, hair (especially goathair) and bristles" along with "laboratory investigators handling the organism." *Id.* at 340.

In arriving at this decision, the Panel considered two sets of data: (1) a human field trial conducted by Drs. Brachman, Glod, Plotkin, Fekety, Werrin, and Ingraham in the 1950's ("Brachman study"), A.R. 3732-45, and (2) surveillance data collected and summarized by the Center for Disease Control ("CDC"). *See* A.R. at 337-38.

The Brachman study involved 1,249 workers in four textile mills that processed imported goat hair. *See* A.R. 3732-33. A portion of the workers received the anthrax vaccine, a portion received a placebo vaccine, and a portion received no treatment. *See* A.R. 3737 (Table 2), A.R. 3736 (Table 4); 50 Fed. Reg. at 51,058 (Panel). During the evaluation period, which included an "outbreak" of inhalation anthrax, twenty-six cases of anthrax occurred. *See* A.R. 3733. The results can best be summarized as follows:

	Total Cases (26)	Anthrax Vaccine	Placebo	No vaccine
Inhalation	5	0	2	3
Cutaneous	21	3 (2 incomplete vaccine)	15 (2 incomplete vaccine)	3

A.R. 3733-36. The Brachman study calculated the effectiveness of the anthrax vaccine at 92.5 percent. *See* A.R. 3737. The authors

of the study based their calculations on a comparison between the placebo and the anthrax vaccine group regardless of the route of exposure.

While relying on the Brachman study for its recommendation of effectiveness, the Panel stated that the study demonstrates "93 percent . . . protection" against only cutaneous anthrax and that "[i]nhalation anthrax occurred too infrequently to assess the protective effect of vaccine against this form of the disease." 50 Fed. Reg. at 51,058 (Panel).

The Panel also considered surveillance data collected by the CDC "on the occurrence of anthrax in at-risk industrial settings." 50 Fed. Reg. at 51,058 (Panel). While twenty-seven cases were observed, no cases occurred in persons who were fully vaccinated. *Id*.

D. FDA's Proposed Rule and Order

In 1985, citing Section 601.25's procedural requirements, FDA published notice of a Proposed Rule to reclassify bacterial vaccines and toxoids covered by the Panel Report. *See* Bio. Prods; Bacterial Vaccines & Toxoids; Implementation of Efficacy Review; Proposed Rule, 50 Fed. Reg. 51,002 (Dec. 13, 1985) ("Proposed Rule").[2] The Proposed Rule adopted the Panel Report

[2] Although 21 C.F.R. § 601.25 contemplates the publication of the report and proposed *order*, FDA called its issuance a "proposed rule."

verbatim with respect to AVA, including the Panel's recommendation to classify AVA as Category I and the Panel's note that "[i]mmunization with this vaccine is indicated only for certain occupational groups with risk of uncontrollable or unavoidable exposure to the organism." *See* 50 Fed. Reg. at 51,058. The Proposed Rule found that "the benefit-to-risk assessment is satisfactory" for this "limited high-risk population." 50 Fed. Reg. at 51,059.

The Proposed Rule required comments "on the proposed classification of products into Category I ... be submitted by March 13, 1986." 50 Fed. Reg. at 51,002. Four total comments were received, none of them specifically addressing the proposal to reclassify AVA. *See* 69 Fed. Reg. 255, 256-259 ("Final Rule and Order"). FDA took no further action until December 30, 2003--eighteen years after the Proposed Rule, but only eight days after this Court's Order enjoining DoD's AVIP.

E. The Law Regarding Unapproved Drugs and Military Personnel

In 1998, in response to concerns about the use of investigational new drugs during the 1991 Gulf War that may have led to unexplained illnesses among veterans, Congress enacted 10 U.S.C. § 1107. This provision prohibits the administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent. The

consent requirement may be waived only by the President. In 1999, the President signed Executive Order 13,139, pursuant to which DoD must obtain informed consent from each individual member of the armed forces before administering investigational drugs and under which waivers of informed consent are granted only "when absolutely necessary." Exec. Order No. 13,139, 64 Fed. Reg. 54,175 (Sept. 30, 1999). In August 2000, DoD formally adopted these requirements in DoD Directive 6200.2.

F. Citizen Petition

On October 12, 2001, a group of individuals filed a citizen petition requesting that FDA declare that AVA is ineffective for use against inhalation anthrax and issue a final order classifying AVA as a Category II product. *See* A.R. 1313-75. The petitioners argued that the Panel had erred in concluding that the Brachman study qualified as a well-controlled field trial for purposes of 21 C.F.R. § 601.25(d)(2). *See* A.R. 1316-17 & n.6. In its August 28, 2002 response, FDA explained that it was "working to complete this rulemaking as soon as possible," and that given "the pendency of this rulemaking," it could not "evaluate the adequacy of the Panel recommendation."[3] A.R. 1378.

[3] Again, although 21 C.F.R. § 601.25 contemplates the publication of a report and proposed order, FDA called its issuance a "proposed rule."

G. The Preliminary Injunction

In March 2003, plaintiffs filed suit in this Court, alleging that the AVIP violates federal law because AVA had never been approved as a safe and effective drug for protection against inhalation anthrax. Plaintiffs asked this Court to enjoin DoD from inoculating them without their informed consent.

On December 22, 2003, this Court issued a Preliminary Injunction enjoining inoculations under the AVIP in the absence of informed consent or a Presidential waiver. Because the record was devoid of an FDA final decision on the investigational status of AVA, the Court was persuaded that AVA was an investigational drug being used for an unapproved purpose in violation of 10 U.S.C. § 1107, Executive Order 13,139, and DoD Directive 6200.2. *See Doe v. Rumsfeld*, 297 F. Supp. 2d 119, 135 (D.D.C. 2003).

H. Final Rule and Order

Eight days after this Court's Preliminary Injunction and eighteen years after FDA proposed to reclassify AVA, the agency announced a Final Rule and Order classifying AVA as a Category I drug. *See* Bio. Prods; Bacterial Vaccines & Toxoids; Implementation of Efficacy Review; 69 Fed. Reg. 255, 265-66 (Jan. 5, 2004)("Final Rule and Order"). The Final Rule and Order stated that AVA was safe and effective "independent of the route of exposure." *See id.* at 257-59. At the same time, FDA issued a

press release noting that a

> recent ruling by a United States District Court for the District of Columbia gave the opinion that the anthrax vaccine should be classified as 'investigational' with regard to protecting against inhalation anthrax. Today's final rule and order make clear that FDA does not regard the approved anthrax vaccine as 'investigational' for protection against inhalation anthrax. FDA's final determination of the safety and effectiveness of the anthrax vaccine, independent of route of exposure, as well as its conclusions regarding the Expert Panel's report, being announced today in the final order are relevant and should be considered in any further litigation in this matter.

See http://www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html.

The Final Rule and Order relied on several sources of data to support its finding of safety and efficacy, including the Brachman Study, the CDC surveillance data, the results of a "small randomized clinical study of the safety and immunogenicity of AVA" conducted by the DoD, "post licensure adverse event surveillance data available from the Vaccine Adverse Event Reporting System (VAERS)," and an independent examination by the Institute of Medicine ("IOM"). *See* Final Rule and Order at 260.

In its discussion, FDA explained, for the first time, certain "points of disagreement with statements in the Panel Report." *See id.* at 259. Specifically, FDA disagreed with the Expert Panel's interpretation of the Brachman Study. FDA concluded:

> because the Brachman comparison of anthrax cases between the placebo and vaccine groups included both inhalation and cutaneous cases, FDA has determined that the calculated efficacy of the vaccine to prevent all types

> of anthrax disease combined was, in fact, 92.5 percent. . . . The efficacy analysis in the Brachman study includes all cases of anthrax disease regardless of the route of exposure or manifestation of disease.

Id. at 259-60.

FDA did note that the five cases of inhalation anthrax were "too few to support an independent statistical analysis." *Id.* at 260. However, FDA explained that:

> of these [five] cases, two occurred in the placebo group, three ocurred in the observation group, and no cases occurred in the vaccine group. Therefore, the indication section of the labeling for AVA does not specify the route of exposure, and the vaccine is indicated for active immunization against *Bacillus anthracis* [anthrax], independent of the route of exposure.

Id.

Moreover, FDA noted that the surveillance data was "supportive of the effectiveness of AVA." *Id.* at 260. FDA also discussed the independent examination by IOM of AVA's safety and effectiveness, during which the IOM Committee "reviewed all available data, both published and unpublished, [and] heard from Federal agencies, the manufacturer and researchers." *Id.* Noting that the abstract of the IOM's Report stated "that AVA, as licensed, is an effective vaccine to protect humans against anthrax including inhalation anthrax," FDA stated it

> agrees with the report's finding that studies in human and animal models support the conclusion that AVA is effective against *B. Anthracis* strains that are dependant upon the anthrax toxin as mechanism or virulence, regardless of the route of exposure.

Id. at 260 & n.5.

I. The Present Case

Following the announcement of FDA's Final Rule and Order, the Court granted defendants' request to stay the Court's earlier Preliminary Injunction except as it applied to the six Doe plaintiffs.[4] *See* Order dated January 7, 2004, at 1-2.

Plaintiffs now ask this Court to vacate FDA's recent Final Rule and Order and to remand the matter to FDA for proper consideration and a determination of the licensing status of AVA. In addition, plaintiffs request that the Court reinstate the injunctive relief, albeit now on a permanent basis, that was granted in its initial ruling of December 22, 2003, because absent a valid final rule and/or order, the Court's conclusion that the vaccine is improperly licensed for inhalation anthrax remains in effect. Alternatively, plaintiffs ask that summary judgment not be granted to defendants and ask that they be permitted to conduct discovery in order to ensure that the administrative record is complete and was not improperly influenced by DoD. Defendants ask this Court to grant summary judgment in their favor.

[4] The parties consented to keeping the Preliminary Injunction in place with regard to the six Doe plaintiffs. Subsequently, at a Motions Hearing on March 15, 2004, the Court vacated its injunction as to the six Doe plaintiffs though the parties agreed that the six Doe plaintiffs would not be required to submit to the vaccination while this lawsuit was pending.

III. Standard of Review

Pending before this Court are cross motions for summary judgment. Summary judgment is granted pursuant to Federal Rule of Civil Procedure 56 only when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The Court views the evidence in the light most favorable to the nonmoving party, according the party the benefit of all reasonable inferences. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Thus, in ruling on cross motions for summary judgment, the Court will grant summary judgment only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not in dispute. *See Rhoads v. McFerran*, 517 F.2d 66, 67 (2d Cir. 1975).

There are no genuine material facts that preclude judgment in this matter. If the FDA's Final Rule and Order categorizing AVA as safe and effective for protection against inhalation anthrax was issued in accordance with the relevant law, then DoD's AVIP is lawful; conversely, if FDA's Final Rule and Order is invalid, the AVIP is unlawful absent informed consent or a Presidential waiver.

Under the Administrative Procedure Act, a reviewing court may hold unlawful and set aside final agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not

in accordance with the law," or "without observance of procedure required by law." 5 U.S.C. § 706(2).

This Court is mindful that the standard of review for agency action is highly deferential. *See American Public Communications Council v. FCC*, 215 F.3d 51, 61 (D.C. Cir. 2000); *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 216 (D.D.C. 1996). Ordinary deference may be heightened even further in cases involving scientific or technical decisions. *See Serono Labs., Inc., v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998) (noting that an agency is entitled to a "high level of deference" when its regulatory determination rests on its "evaluation [] of scientific data within its area of expertise"). The "determination whether a drug is generally recognized as safe and effective within the meaning of [the FDCA] necessarily implicates complex chemical and pharmacological considerations." *Weinberger v. Bentex Pharms, Inc.*, 412 U.S. 645, 654 (1973). FDA's "judgment as to what is required to ascertain the safety and efficacy of drugs" thus falls "'squarely within the ambit of FDA's expertise and merit[s] deference from' the courts." *Bristol-Myers*, 923 F. Supp. at 220 (quoting *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir.), *cert denied*, 516 U.S. 907 (1995)).

Although FDA's scientific expertise is due great deference, it is well within this Court's scope of authority to ensure that

the agency adheres to its own procedural requirements. *See Service v. Dulles*, 354 U.S. 363 (1957) (seminal case standing for the proposition that judicial review is available to ensure that agencies comply with their own voluntarily-promulgated regulations, even where Congress has given the agency "absolute discretion" over the administrative action in question). *See also Rodway v. United States Dept. of Agric.*, 514 F.2d 809, 813-14 (D.C. Cir. 1975) (requiring the agency to comply with its own regulations "making the procedural requirements of [the APA] applicable" because "it is, of course, well settled that validly issued administrative regulations have the force and effect of law") (citing *Morton v. Ruiz*, 415 U.S. 199, 235 (1974); *Vitarelli v. Seaton*, 359 U.S. 535, 539-540 (1959); *Service*, 354 U.S. at 388). In this case, the Court focuses not on FDA's substantive--and highly technical--determinations regarding the safety of AVA, but rather on whether or not the Agency observed the relevant "procedure required by law."

IV. Discussion

A. Standing

The party asserting jurisdiction always has the burden to prove standing. *FW/PBS Inc. v. City of Dallas*, 492 U.S. 21, 23 (1990). To have standing, a plaintiff must allege: (1) an "actual or imminent" injury-in-fact; (2) "fairly . . .

trace[able] to the challenged action of the defendant"; and (3) "likely" to be "redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). At the summary judgment stage, "the plaintiff can no longer rest on . . . 'mere allegations'," but must "'set forth' by affidavit or other evidence 'specific facts'" establishing standing. *Lujan*, 504 U.S. at 561 (quoting Fed. R. Civ. P. 56(e)).

The Court has recognized that in order to establish injury plaintiffs must demonstrate that they have taken, or have been ordered imminently to take, the anthrax vaccine. *See Doe*, 297 F. Supp. 2d at 130-31. While defendants argue that plaintiffs have presented no "specific facts" in support of these claims, the Court accepts and credits the sworn affidavit of plaintiffs' counsel. Thus, plaintiffs have standing to challenge the FDA's actions.

B. The Status of FDA's December 30, 2003 Issuance

At the outset, the parties dispute whether the FDA's December 30, 2003 issuance, labeled a "Final Rule and Order," was in fact a Final Rule or a Final Order.[5] The Court will address this issue in the first instance.

The APA defines two broad, normally mutually exclusive

[5] Defendants claim that while part of the issuance is a Rule, the part that is relevant to AVA is an Order. Tr. 5/25/04 at 38.

categories of agency action - rules and orders. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 216 (1988)(Scalia, J., concurring) (distinction between rules and orders is "the entire dichotomy upon which the most significant portions of the APA are based"). The APA defines a "rule" as:

> the whole or a part of an agency statement of general or partial applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganization thereof, prices, facilities, appliances, services, or allowance therefor or of valuation, costs, or accounting, or practices bearing on any of the foregoing.

5 U.S.C. § 551(4). "[R]ule making," which can be formal or informal, is the "agency process for formulating, amending, or repealing a rule." *Id.* at § 551(5).

When promulgating a substantive rule, an agency must comply with the notice-and-comment requirements of 5 U.S.C. § 553. *See* 5 U.S.C. § 553(b). Notice and comment requires that an agency provide notice of a proposed rulemaking, and that notice must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). Once a proposed rule is issued, the agency must "give interested persons an opportunity to participate in the rulemaking through submissions of written data, views, or arguments." 5 U.S.C. § 553(c).

The APA defines an "order" as:

> the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other then rule making but including licensing.

Id. at § 551(6). "Adjudication," which can also be formal or informal, is the "agency process for the formulation of an order." *Id.* at § 551(7).

Plaintiffs claim that in conducting its review of AVA, FDA acted in a manner consistent with the exercise of rulemaking and that it was not until the present litigation that defendants sought to recast the AVA certification process.[6] Plaintiffs allege that FDA's rulemaking denied affected parties the opportunity to effectively participate in the process, and that the Final Rule should be invalidated and remanded to the agency.

Defendants argue that a decision by FDA to place a biological product in Category I, thereby confirming its license, falls squarely within the definition of an "order" for purposes of the APA. *See* 5 U.S.C. § 551(6). Defendants note that Section 601.25 itself refers to FDA's determination as an "order." *See* 21 C.F.R. § 601.25(f). Defendants observe that FDA's process for licensing biological products is not itself subject to rulemaking requirements. *See, e.g.,* 42 U.S.C. § 262(a)(2)(A)("[t]he

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[6] Plaintiffs note that the original notice of final agency action that appeared in the Federal Register on January 5, 2004 described FDA's actions as a "Final Rule." The words "and Order" were added by hand. Until that final agency action, FDA and DoD spokespersons have consistently referred to this determination concerning AVA as a "Final Rule." *See* Pls.' Reply Brief 6-7.

Secretary shall establish, by regulation, requirements for approval, suspension, and revocation of biologics licenses"); 21 C.F.R. §§ 601.2 - 601.9. Thus, defendants note that were AVA a new biological product for which the manufacturer was seeking an initial license, FDA would not be required by the APA's rulemaking provision to publish its licensing decision for notice and comment.

Moreover, defendants allege that FDA's decision placing AVA in Category I bears none of the hallmarks of a "rule." It does not "implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). Instead, defendants claim, the decision merely applies already-existing legal standards to specific facts - the hallmark of adjudication. Defendants note that the decision has no "future effect" (5 U.S.C. § 551(4)); it merely determines the "past and present rights and liabilities" of AVA's manufacturer with respect to an already-issued license. *See Bowen*, 488 U.S. at 219 (Scalia, J., concurring); *see also Goodman v. FCC*, 182 F.3d 987, 994 (D.C. Cir. 1999). Defendants submit that consistent with Section 601.25(g), FDA referred to its licensing decision as a "Final Order" in several places. *See* Final Rule and Order at 257.

Plaintiffs claim that FDA has considered determinations like the one issued regarding AVA as rulemaking subject to judicial review. In *Contact Lens Manufacturers Ass'n v. FDA*, a commercial

association sued FDA over its decision to classify contact lenses according to the product's safety and effectiveness. 766 F.2d 592, 594 (D.C. Cir. 1985). In describing the safety and effectiveness of the lenses, FDA utilized a three class categorization system. Contact lens manufacturers whose products had been placed in Class III lobbied to reverse FDA's proposal to stop a transfer of a category of lenses from Class III to Class I. Plaintiffs claim that the determination made by FDA with regard to the products' status are virtually identical to the determination at issue here. Nevertheless, FDA provided extensive comment periods, and even a public hearing. *Id.* at 596-7.

In *Cutler v. Hayes*, FDA engaged in a comprehensive review of the safety and effectiveness of all over-the-counter drugs. 818 F.2d 879 (D.C. Cir. 1987). In doing so, FDA used a process, again, virtually identical to the one at issue here. To start, advisory review panels of experts were appointed to analyze existing test data and make recommendations in the form of monographs. *Id.* at 884. FDA reviewed the monographs, published them in the Federal Register, opened the period for public comment, and made a final recommendation, which was also open for public comment. *Id.* FDA then promulgated a determination classifying the drug as either Category I (safe and effective), Category II (not generally recognized as safe and effective), or

Category III (data is insufficient to classify as I or II). In making its determination, FDA invited public comment twice.

Defendants acknowledge that FDA did provide interested parties an opportunity to comment on its Proposed Order categorizing AVA as a Category I product. Defendants argue that while agencies have discretion to employ "extra procedural devices," the court may not second guess the agency's decision not to do so. *See Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.* 435 U.S. 519, 545 (1978).

The D.C. Circuit has explained that when determining whether agency action is rulemaking or adjudicating:

> the focus is not on whether the particular proceeding involved trial-type devices but instead turns on the nature of the decision to be reached in the proceeding. Rulemaking is prospective in scope and nonaccusatory in form, directed to the implementation of general policy concerns into legal standards. Adjudication, on the other hand, is "individual in impact and condemnatory in purpose," directed to the determination of the legal status of a particular person or practices through the application of preexisting legal standards.

FTC v. Brigadier Industries Corp., 613 F.2d 1110, 1117 (D.C. Cir. 1979).

It appears to the Court that the agency held AVA up to a pre-determined standard and made a judgment as to whether to classify AVA as safe and effective or otherwise. This suggests to this Court that FDA has issued an order. However, Section 601.25(g) and (i) instruct the agency to take comments for 90 days. While orders typically fall outside the confines of APA

rulemaking, *see* 5 U.S.C. § 553, here, the Court is confronted with a situation where the agency decided that notice and comment regarding the proposed order was the correct course of action. This procedure is not without precedent.[7]

In *Contact Lens Manufacturers*, the FDA reviewed products for safety and efficacy, provided opportunity for public input through the notice-and-comment process and public hearings, and published an Order as is evidenced by the D.C. Circuit's labeling of its review as a "Petition for Review of an *Order* of the Food and Drug Administration." 766 F.2d at 593 (emphasis added). *Cutler* also provided an opportunity for the public to submit comments following the publication of a proposed order. *See* 818 F.2d at 884. Thus, the Court is persuaded that the December 30, 2003 issuance was an order. While orders do not ordinarily require notice and comment, the plain meaning of Section 601.25 of FDA's regulations requires notice and comment on the classification of the biologics in question:

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[7] The Court is perplexed by the fact that both parties have looked at *Contact Lens Manufacturers* and *Cutler* and asserted that rulemaking took place. *See* Tr.5/25/04 (by counsel for defendants "Let me cut to the chase, *Contact Lens* involved what was a rule. It wasn't an order because it dealt with a broad category." The Court: "So it's the government view that it was a rule that was being challenged?" Counsel: "That was a rule." The Court: "And not an Order?" Counsel: "And unquestionably not an order."); *see also* Pls.' Reply at 4 ("A review of comparable FDA determinations [alluding to *Contact Lens Manufactures* and *Cutler*] demonstrates that this type of FDA action constitutes rulemaking subject to public comment."

> (4) The full report or reports of the panel to the Commissioner of Food and Drug. The summary minutes of the panel meeting or meetings shall be made available to interested persons upon request. Any interested person may within 90 days after publication of the proposed order in the Federal Register, file with the Hearing Clerk of the Food and Drug Administration written comments in quintuplicate. . . .
> (g) Final order. After reviewing the comments, the Commissioner of Food and Drugs shall publish in the Federal Register a final order on the matters covered in the proposed order.

21 C.F.R. § 601.25(f)(4) & (g). This requirement is also reflected in FDA's Final Rule and Order:

> In accordance with § 601.25, after reviewing the conclusions and recommendations of the review panel, FDA would publish in the Federal Register a proposed order . . . After reviewing public comments, FDA would publish a final order on the matters covered in the proposed order.

69 Fed. Reg. 255.

Notice and comment gives interested parties an opportunity to participate through the submission of data, views and arguments.[8] See *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, Inc., 435 U.S. 519 (1978). Notice and comment also ensures fairness to all parties and provides a well-developed record - something this case is severely lacking. *See Sprint Corp v. FCC*, 315 F.3d 369 (D.C. Cir. 2003); *see also* Tr. 5/25/04 at 2 (by the Court "Let me just say at the outset

[8] It appears to the Court that the FDA was concerned about representation of divergent views as section 601.25(a) notes that the advisory review panels "shall include persons from lists submitted by organizations representing professional, consumer, and industry interests. Such persons shall represent a wide divergence of responsible medical and scientific opinion."

that the administrative record in this case is one of the most confusing, jumbled records this Court has ever seen. Indeed, the only thing that is clear is that confusion abounds.").

Although defendants are correct that the courts may not compel an agency to employ "extra procedural devices," this Court shall compel an agency to follow the procedures set forth in its own regulations. In this case, FDA's regulations require it to: (1) publish a proposed order in the Federal Register after considering the expert panel's recommendations; (2) provide 90 days for interested persons to file written comments on the proposal; and (3) publish a final order on the matters covered in the proposed order. *See* 21 C.F.R. § 601.25 (f)(4) & (g). Thus, this Court will concentrate its review on the sufficiency of FDA's compliance with these procedures. To guide its analysis, the Court will look to the substantial body of existing case law that gives meaning to what is meant by "notice and comment" under the APA.

C. Procedural Challenges to FDA's Final Rule and Order

1. Studies Outside the Comment Period

The public was invited to submit comments on the Proposed Order for 90 days, from December 13, 1985, until the period closed on March 13, 1986. However, eighteen years later when the Final Rule and Order was published, FDA relied on studies

and data that were not in existence at the conclusion of the comment period. Plaintiffs argue that the D.C. Circuit has frowned on this practice, noting that "[a]n agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." *Conn. Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530-31 (D.C. Cir. 1982). It is clear that when an agency relies on studies or data after the comment period has ended, no meaningful commentary on such data is possible. *See American Iron & Steel Inst. v. OSHA,* 939 F.2d 975, 1009-10 (D.C. Cir. 1991); *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 540-41 (D.C. Cir. 1983); *Sierra Club v. Costle*, 657 F.2d 298, 398 (D.C. Cir. 1981).

In *American Iron & Steel*, OSHA relied on a professional industry analysis that was completed after the comment period had ended in evaluating the economic feasibility of certain workplace exposure levels. The D.C. Circuit held that "reliance on the [post-comment period data] without providing an opportunity for comment was improper," and the court vacated the portion of the regulation that relied on the late data. *See* 939 F.2d at 1010.

Here, plaintiffs argue that FDA relied on at least four extensive studies that commenced and concluded after the comment period ended. *See* 69 Fed. Reg. at 265-66. For example, FDA

cites and relies on a report on the anthrax vaccine issued by the Institute of Medicine ("IOM") in 2002 - sixteen years after the comment period ended. *Id.* at 259-60. In issuing its report, the IOM evaluated "all available data, both published and unpublished" on the anthrax vaccine, specifically focusing on three studies from 1996, 1998, and 2001. *Id.* at 260 & n.5.

Moreover, plaintiffs note that of the 4,209 pages in the administrative record, approximately 2,653 (63%) post-date 1986. Plaintiffs allege that persons who submitted comments in late 1985 and early 1986 were deprived of the opportunity to comment on these studies. Plaintiffs argue that this procedural flaw is so fundamental as to require the invalidation of FDA's Final Rule and Order.

2. Deviations From The Proposed Rule

While "a final rule need not be identical to the original proposed rule," when the final rule "deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal." *AFL-CIO v. Donavan*, 757 F.2d 330, 338 (D.C. Cir. 1985). The test is whether the final rule is a "logical outgrowth" of the proposed rule. If "a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule," then the final rule is

not a "logical outgrowth." *American Water Works Assoc. v. EPA*, 40 F.3d 1266, 1274 (D.C. Cir. 1994). *See also Nat'l Mining Assoc. v. Mine Safety & Health Admin.*, 116 F.3d 520, 531 (D.C. Cir. 1997).

In *Shell Oil Co. v. EPA*, plaintiffs asserted that the EPA's Final Rule contained a definition of "hazardous waste" that was much broader than the definition contained in the proposed rule and, as a result, they claimed not to have notice of the definition that was finally adopted. 950 F.2d 741, 748 (D.C. Cir. 1991). EPA argued that it intended to include the broader aspects of the definition, and that interested parties should have anticipated the substance of the final rule. *Id.* at 749-50. In setting aside the rule and remanding it to the EPA, the D.C. Circuit held that an agency's "unexpressed intention cannot convert a final rule into a 'logical outgrowth' that the public should have anticipated. Interested parties cannot be expected to divine the EPA's unspoken thoughts." *Id.* at 751-52.

Defendants argue that FDA's Final Rule and Order is identical to what it proposed in 1985 - to place AVA in Category I. *Compare* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51,002, 51,104 (Dec. 13, 1985) *with* Final Rule and Order at 259. They claim that plaintiffs' position is based on a misunderstanding of the Expert Panel's recommendation. Defendants state that when the

Panel issued its report, AVA was indicated for persons at risk to exposure to the anthrax bacterium and its label did not specify a route of exposure. *See* 50 Fed. Reg. at 51,059.

Moreover, defendants contend that the Panel recommended Category I notwithstanding the Panel's alleged erroneous belief that the Brachman study did not assess the protective effect of the vaccine against inhalation anthrax. Defendants claim that this "framed . . . for discussion" whether AVA should be placed in Category I for use against inhalation anthrax. *See Omnipoint Corp. v. FCC*, 78 F.3d 620, 631 (D.C. Cir. 1996). Thus, defendants argue that FDA provided adequate "opportunities for interested parties to offer comments that could persuade the agency to modify its rule." *See American Water Works,* 40 F.3d at 1274.

However, the Court finds that the public has never been afforded an opportunity to comment on the safety and efficacy of AVA as it pertains to inhalation anthrax. FDA's Proposed Order (though called a "Proposed Rule" when published) only contained the Panel's assessment of AVA. It found that the anthrax vaccine was safe and effective in "the limited circumstances for which this vaccine is employed." 50 Fed. Reg. at 51,059. At that time, the vaccine was employed for use by "certain occupational groups," mainly "individuals in industrial settings" who worked with animal furs, hides and hairs. 50 Fed.

Reg. at 51,058. The vaccine's use was intended to be for "protection against cutaneous anthrax in fully immunized subjects." 50 Fed. Reg. at 51,059. The Panel concluded that, "no meaningful assessment of the [the vaccine's] value against inhalation anthrax is possible." *Id.* It was under this premise that the public was on notice to submit comments.

Interested parties in 1985 could not have anticipated that FDA would permit the vaccine to be used for inhalation anthrax as a result of exposure through a biological attack.[9] In 1985 there would have been no reason to submit comments on the vaccine's use against other routes of exposure for the population at large; indeed, not a single comment was received on anthrax in response to the Proposed Rule.

Now, for the first time, eighteen years later, FDA's Final

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[9] Defendants' counsel conceded as much in response to a question by the Court: "But it's absolutely right, Your Honor, that the possibility of weaponized anthrax was not in the minds of the advisory panel and probably not in the minds of the FDA." Tr. 5/25/04 at 69.

Lending further support to the notion that the Expert Panel did not consider mass inhalational anthrax exposure is the Panel's own comment:

> Anthrax vaccine poses no serious special problems other than the fact that its efficacy against inhalation anthrax is not well documented. This question is not amenable to study due to the low incidence and sporadic occurrence of the disease. In fact, the industrial setting in which the studies above were conducted is vanishing, precluding any further clinical studies. In any event, further studies on this vaccine would receive low priority for available funding.

50 Fed. Reg. 51,058.

Rule and Order asserts that FDA "does not agree with the Panel report," and believes that "the vaccine is indicated for active immunization against [anthrax], independent of the route of exposure," and that the vaccine will "protect humans against . . . inhalation anthrax." 69 Fed. Reg. at 259-60.

The Court finds that this significant post-comment expansion of the scope of FDA's inquiry deprived the public of a meaningful opportunity to submit comments and participate in the administrative process mandated by law. Because "a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade" the FDA to change its position with regard to the use of AVA against inhalation anthrax, the Agency's Final Rule and Order is by no means a "logical outgrowth" of the 1985 Proposed Rule. *See American Water Works,* 40 F.3d at 1274. This failure to provide for a meaningful opportunity to comment, as required by FDA's own regulations, violates the APA. *See* 5 U.S.C. § 706(2).

While vacatur is the normal remedy for an APA violation, a plaintiff must "show prejudice from an agency's procedural violation." *City of Waukesha v. EPA*, 320 F.3d 228, 246 (D.C. Cir. 2003). For a plaintiff to establish prejudice on the basis of a "logical outgrowth" argument, a plaintiff generally must show (1) that, "had proper notice been provided, they would have submitted additional, different comments that could have

invalidated the rationale for the revised rule;" or (2) that "the agency has entirely failed to comply with the notice-and-comment requirements, and the agency has offered no persuasive evidence that possible objections to its final rules have been given sufficient consideration." *Id.*

Defendants argue that plaintiffs cannot make the first showing because FDA did consider and reject arguments against the rationale for its effectiveness determination in the course of responding to the citizen petition. *See, e.g.,* A.R. 1376-85. In its Final Rule and Order, FDA expressly referred to the citizen petition and its response. *See* FDA Rule and Order at 259 n.2. Further, defendants claim that FDA's citizen petition response provides "persuasive evidence" that it considered fully "possible objections" to the Order. *See City of Waukesha*, 320 F.3d at 246.

However, the Court is not persuaded. While some individuals may have submitted comments as part of a citizen petition, it is clear to this Court that if the status of the anthrax vaccine were open for public comment today, the agency would receive a deluge of comments and analysis that might inform an open-minded agency. Airborne exposure to anthrax was not an indication under the licensing contemplated by the 1985 Proposed Rule and a new notice-and-comment period would be the first opportunity that interested parties would have to

challenge the vaccine's efficacy against such exposure.

Thus, the Final Rule and Order shall be vacated and remanded to the agency for reconsideration following an appropriate notice-and-comment period in accordance with the APA, the Agency's own regulations, and this Memorandum Opinion and Order.[10]

V. Scope of Injunction

Having vacated and remanded FDA's Final Rule and Order, the posture of this case reverts back to where it was on December 22, 2003, when this Court granted plaintiffs' Motion for a Preliminary Injunction. Thus, for all the reasons stated in this Court's December 22, 2003 opinion, including Congress's prohibition on forced inoculations with "investigational" drugs, *see* 10 U.S.C. § 1107, the Court shall now issue a permanent injunction. Unless and until FDA follows the correct procedures to certify AVA as a safe and effective drug for its intended use, defendant DoD may no longer subject military personnel to involuntary anthrax vaccinations absent informed consent or a Presidential waiver.

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[10] Because the Court is granting plaintiffs' Motion for Summary Judgment, this Memorandum Opinion does not address plaintiffs' alternative argument for discovery or defendants' Motion for Summary Judgment. Moreover, since the Court's holding is based on procedural grounds, the Court does not reach plaintiffs' numerous substantive challenges to FDA's Final Rule and Order.

In the days after the Court issued its injunction, there was much discussion concerning whether the injunction applied to the six Doe plaintiffs or whether the injunction applied to all persons affected by the DoD's involuntary anthrax program. Because it is inevitable that this concern will be raised again, the Court shall address it now.[11]

Traditionally, "[l]itigation is conducted by and on behalf of the individual named parties only." *Califano v. Yamasaki*, 442 U.S. 682, 700-01 (1979). This general rule is based on the fundamental principles of due process and prudential standing. *See, e.g., Allen v. Wright*, 468 U.S. 737, 751 (1984)(noting "the general prohibition on a litigant's raising another person's legal rights"); *Singleton v. Wulff*, 428 U.S. 106, 113-14 (1976) ("[C]ourts should not adjudicate [the] rights [of third persons] unnecessarily, and it may be that in fact the holders of those rights either do not wish to assert them, or will be able to enjoy them regardless of whether the in-court litigant is successful or not.").

However, the Court notes that this litigation concerns the lawful status of the anthrax vaccine. Having found that the vaccine's use without informed consent or a Presidential waiver

[11] The parties briefed this issue in early 2004 which culminated in a Motions Hearing on March 15, 2004. At that time, the Court expressed its concern that a finding on this issue would have resulted in an advisory opinion. Thus, the Court denied the motion without prejudice.

is unlawful, this Court would be remiss to find that a conflict exists between service members who think that the DoD should be required to follow the law and those service members who think otherwise.

_____The Fourth, Fifth, Ninth, and D.C. Circuits have held that an injunction can benefit parties other than the parties to the litigation. *See, e.g., National Mining Ass'n, et. al., v. U.S. Army Corps of Engineers, et. al.,* 145 F.3d 1399 (D.C. Cir. 1998); *Bresgal v. Brock*, 843 F.2d 1163 (9th Cir. 1987); *Evans v. Harnett County Bd. of Educ.*, 684 F.2d 304 (4th Cir. 1982); *Meyer v. Brown & Root Construction Co.,* 661 F.2d 369 (5th Cir. 1981). The Supreme Court has implicitly agreed with this proposition. *Lujan v. National Wildlife Federation*, 497 U.S. 871, 913 (1990).

"There is no general requirement that an injunction affect only the parties in the suit. Where, as here, an injunction is warranted by a finding of defendants' outrageous unlawful practices, the injunction is not prohibited merely because it confers benefits upon individuals who were not named plaintiffs or members of a formally certified class." *McCargo v. Vaughn*, 778 F. Supp. 1341, 1342 (E.D. Pa. 1991). A district court has "broad power to restrain acts which are of the same type or class as unlawful acts which the court has found to have been committed or whose commission in the future, unless enjoined,

may fairly be anticipated from the defendant's conduct in the past." *N.L.R.B. v. Express Publ'g Co.*, 312 U.S. 426, 435 (1941).

The D.C. Circuit has found that when agency "regulations are unlawful, the ordinary result is that the rules are vacated – not that their application to the individual petitioner is proscribed." *National Mining Ass'n*, 145 F.3d at 1409 (citation omitted). In *National Mining Ass'n*, the district court invalidated a Corps of Engineers regulation and entered an injunction prohibiting the Corps and the Environmental Protection Agency from enforcing the regulation nationwide. 145 F.3d at 1408. The D.C. Circuit upheld that nationwide application, notwithstanding the fact that non-parties to the litigation would specifically be affected. *Id.* at 1409-10.

Government-wide injunctive relief for plaintiffs and all individuals similarly situated can be entirely appropriate and it is "well-supported by precedent, as courts frequently enjoin enforcement of regulations ultimately held to be invalid." *Sanjour v. United States EPA*, 7 F. Supp. 2d 14, 17 (D.D.C. 1998). *See, e.g., Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989)(court decision invalidating unlawful agency regulation applies beyond just individual petitioners); *Planned Parenthood Fed'n of Amer., Inc., v. Heckler*, 712 F.2d 650 (D.C. Cir. 1983)(affirming final injunction prohibiting enforcement of

invalidated regulations); *Dimension Fin. Corp. v. Board of Governors of the Fed. Reserve Sys.*, 744 F.2d 1402 (10th Cir. 1984)(enjoining Board from enforcing or implementing invalid regulations) *aff'd*, 474 U.S. 361 (1986); *Service Employees Int'l Union v. General Servs. Admin.*, 830 F. Supp. 5 (D.D.C. 1993)(invalidating GSA regulation and enjoining further enforcement of the rule).

The Supreme Court has also embraced this view. Although written as part of a dissent, the D.C. Circuit has noted that it expressed the views of all nine Justices. Justice Blackmun wrote:

> The Administrative Procedure Act permits suit to be brought by any person 'adversely affected or aggrieved by agency action.' In some cases, the 'agency action' will consist of a rule of broad applicability; and if the plaintiff prevails, the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual. Under these circumstances, a single plaintiff, so long as he is injured by the rule, may obtain 'programmatic' relief that affects the rights of parties not before the court. On the other hand, if a generally lawful policy is applied in an illegal manner on a particular occasion, one who is injured is not thereby entitled to challenge other applications of the rule.

Lujan, 497 U.S. at 913 (Blackmum, J. dissenting)(citation omitted). *See also id.* at 890 n.2 (majority opinion)(noting that under the APA, successful challenge by aggrieved individual can affect the entire agency program)(as cited in *National Mining Ass'n*, 145 F.3d at 1409).

However, defendants are correct in asserting that *National*

Mining Ass'n did not address a mandatory rule that requires district courts to issue nationwide injunctions as a matter of law in all cases where agency regulations are invalidated. Rather, the appropriate scope is in the court's discretion. *See* 145 F.3d at 1408-09 (noting the district court's "discretion in awarding injunctive relief" and holding that when "a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated"). Courts retain discretion to decline granting an injunction even where there is a conceded violation of law. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13 (1982).

Defendants attempt to distinguish *National Mining Ass'n* from the present case by noting that the injunction there prohibited the enforcement by an agency of its own broadly applicable regulation deemed by the court to be facially invalid. *See* 145 F.3d at 1408. Here, plaintiffs seek an injunction that would prohibit DoD from taking action with respect to individual members of the military. Defendants claims that this is much broader than the injunction in *National Mining Ass'n.*[12]

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[12] Defendants also challenge the stability of *National Mining Ass'n* in the D.C. Circuit. Defendants note that the D.C. Circuit has recently questioned the viability of *National Mining Ass'n* for overlooking a key Supreme Court case in considering which test to apply to determine the merits of plaintiff's facial challenge. *See Amfac Resorts v. United States Dep't of Interior*, 282 F.3d 818, 826-27 (D.C. Cir. 2002) *rev'd on other grounds*, 538

Defendants note that the relief in *National Mining Ass'n* was also understandable in light of the broad representation of the plaintiffs before the court there. That case involved a challenge brought by several trade associations on behalf of their members. 145 F.3d at 1401. Defendants claim that the trade associations represented a much broader cross-section of affected parties than the six Doe plaintiffs.

However, it appears to this Court that the Court is faced with precisely the circumstances described by Justice Blackmun in his discussion of "programmatic relief." *See also Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 212 (D.D.C. 2002)(noting that *National Mining Ass'n* stands for the "proposition that a nationwide injunction invalidating an agency rule of broad applicability is appropriate even where a single plaintiff has challenged the legality of the rule"). Thus, the injunction issued today shall apply to all persons subject to DoD's involuntary anthrax inoculation program and not just the six Doe plaintiffs.

U.S. 803 (2003); *National Mining Ass'n v. United States Dep't of Interior*, 251 F.3d 1007, 1010 (D.C. Cir. 2001). However, in *Amfac Resorts*, the D.C. Circuit "called into question its holding regarding the dredging regulation." *Id.* at 826-27. Thus, the D.C. Circuit reconsideration of the standard it applied in its analysis of a constitutional challenge to the dredging regulation does not suggest that program-wide relief cannot be extended to non-plaintiffs.

VI. Conclusion

This Court has an obligation to ensure that FDA follow the law in order to carry out its vital role in protecting the public's health and safety. By refusing to give the American public an opportunity to submit meaningful comments on the anthrax vaccine's classification, the agency violated the Administrative Procedure Act. While the policy of submitting comments on an agency's proposed order may be unusual, it is the course the agency chose to take and this Court shall ensure that the agency follows through on its commitment to the public.

Congress has prohibited the administration of investigational drugs to service members without their consent. This Court will not permit the government to circumvent this requirement. The men and women of our armed forces deserve the assurance that the vaccines our government compels them to take into their bodies have been tested by the greatest scrutiny of all - public scrutiny. This is the process the FDA in its expert judgment has outlined, and this is the course this Court shall compel FDA to follow.

Accordingly, it is by the Court hereby

ORDERED that Plaintiff's Motion for Summary Judgment is **GRANTED**. The FDA's Final Rule and Order is vacated and shall be remanded to the agency for reconsideration in accordance with this Memorandum Opinion and Order. Unless and until FDA

properly classifies AVA as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. § 1107. Accordingly, the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver; and it is further

ORDERED that, in light of the finding with regard to Plaintiffs' Motion for Summary Judgment, Defendants' Motion for Summary Judgment is **DENIED.**

A separate Order and Judgment accompanies this Memorandum Opinion.

Signed: Emmet G. Sullivan
United States District Judge
October 27, 2004

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

APR 2 9 2005

PERSONNEL AND
READINESS

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

SUBJECT: Implementation of Resumption of the Anthrax Vaccine Immunization Program (AVIP) Under Emergency Use Authorization (EUA)

References: (a) Deputy Secretary of Defense Memorandum, "Resumption of the Anthrax Vaccine Immunization Program (AVIP) Under Emergency Use Authorization (EUA)," April 25, 2005

(b) Food and Drug Administration: Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability, 70 *Federal Register* 5452-5256, February 2, 2005 (WWW.FDA.GOV/CBER/VACCINE/ANTHRAXEUA.HTM)

Reference (a) directed the Military Services to amend their anthrax vaccination plans to resume the AVIP under conditions set forth in the EUA issued January 27, 2005 (reference (b)) and directed the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) to issue these detailed instructions to implement that resumption.

1. Applicability and Scope.

The following categories of individuals are eligible for vaccination under the EUA.

1.1. Uniformed personnel, to include forces afloat, and civilian and contract Mariners under Commander, Military Sealift Command serving in the Central Command area of responsibility for 15 or more consecutive days.

1.2. Uniformed personnel assigned to the Korean Peninsula for 15 or more consecutive days.

1.3. Uniformed personnel assigned to special mission units, units with biowarfare- or bioterrorism-related missions, and other specially designated missions, as recommended by the Chairman of the Joint Chiefs of Staff (or designee) and approved by the USD(P&R).

1.4. Upon notification by the Executive Agent that appropriate consultation procedures have been completed, emergency-essential and equivalent DoD civilian employees assigned for 15 or more consecutive days to the U.S. Central Command area of responsibility or Korea. For this purpose, "equivalent" personnel means other personnel whose duties meet all the requirements of 10 U.S.C. § 1580, but who have not been designated as "emergency-essential."

1.5. DoD contractor personnel carrying out mission-essential services and assigned for 15 or more consecutive days to the U.S. Central Command area of responsibility and Korea, if provided for in the contract.

1.6. In the U.S. Central Command area of responsibility and Korea, the following categories of individuals, upon request:

1.6.1. U.S. government civilian employees and U.S. citizen contractor personnel other than those referred to in paragraphs 1.4 and 1.5.

1.6.2. Adult family members, 18-65 years of age, accompanying DoD military and civilian personnel.

1.6.3. U.S. citizen adult family members, 18-65 years of age, accompanying U.S. contractor personnel if provided for in the contract.

1.7. Other individuals approved by USD(P&R), consistent with reference (b). The Secretaries of the Military Departments, Commandant of the Coast Guard, and Combatant Commanders may, based on critical mission impact, recommend to USD(P&R) for eligibility for vaccination under the EUA other personnel who are at heightened risk of exposure due to attack with anthrax.

2. EUA Condition: Information to Healthcare Providers.

As required by reference (b), a condition of the EUA is that the Services and affected Defense Agencies shall implement an educational and information program for healthcare providers and authorized dispensers (i.e., vaccinators) conducting the vaccinations. The following requirements apply.

2.1. This education program will inform healthcare providers that:

a. The FDA has issued the EUA for preventing inhalation anthrax,

b. Of the significant known and potential benefits and risks of anthrax vaccination (and the extent to which benefits and risks are unknown),

c. That no other product is approved by FDA to prevent anthrax before exposure,

d. Of the non-vaccine alternatives that are available and of their risks and benefits.

It will also provide them the information that must be provided to potential vaccine recipients under section 3, below.

2.2. The manufacturer's package insert will be distributed with all vials of anthrax vaccine and will be available to healthcare providers and vaccinators. The insert also appears at www.bioport.com/AnthraxVaccine/Insert/AVAInsert.asp.

2.3. Healthcare-access guidance for all active, reserve, civilian and contractor personnel, and others affected by this policy will be provided. Guidance shall include, as appropriate, information on access to care for personnel located near or on a military installation, in a remote location, or in a travel duty or leave status.

2.4. Additional education and information materials for providers will be provided through the Executive Agent, and will be available electronically at www.anthrax.mil/eua.

2.5. Healthcare providers and vaccinators shall be familiar with all educational information provided to recipients, including the option to refuse information.

3. Condition of EUA: Information to Potential Recipients and Option to Refuse.

AVIP is a Commander's program. As required by reference (b), Commanders shall implement an educational and information program for potential recipients of vaccination and assure that they have the option to refuse. The following requirements apply.

3.1. This education program will inform potential recipients that the FDA has issued the EUA for preventing inhalation anthrax, of the significant known and potential benefits and risks of anthrax vaccination (and the extent to which such benefits and risks are unknown), that no other product is approved by FDA to prevent anthrax before exposure, that individuals have the option to accept or refuse anthrax vaccination, of the potential health and mission consequences of refusing administration, and of the alternatives to vaccination and of their risks and benefits.

3.2. All individuals eligible for anthrax vaccination under the EUA will be informed that: "You may refuse anthrax vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination."

3.3. Personnel identified in paragraphs 1.1 through 1.5, above, shall be informed: "Your military and civilian leaders strongly recommend anthrax vaccination."

3.4. The required mode of providing this education to individuals will take the form of the AVIP trifold brochure – EUA Edition – dated April 5, 2005, or later. Each individual will be provided a copy of this brochure before being offered the vaccination. Through sign-in log or similar means, a record will be established to document that the trifold brochure was provided.

3.5. The brochure will be supplemented with education via, whenever possible, a set of standard briefing slides. Education and information materials for potential recipients will be provided through the Military Vaccine Agency, and be available electronically at www.anthrax.mil/eua.

3.6. Military leaders at all levels will respect this option to refuse during the EUA period. For individuals who express initial doubts about the value of anthrax vaccination, counseling may reinforce education and information messages and answer questions or concerns, but may not coerce.

3.7. Individuals referred to in paragraphs 1.1 through 1.5, above, who have refused anthrax vaccination during the EUA period should not be offered anthrax vaccination again, except in changed circumstances (e.g., at a new duty location, after the passage of a substantial period of time, such as 30 or more days). However, an individual eligible for anthrax vaccination may change his or her mind at any time and receive vaccination.

4. Record-Keeping.

Each Component is responsible for implementing a comprehensive immunization tracking system that incorporates member data, unit data, date of vaccination, and vaccine lot information. Each Service shall monitor documentation of immunization data. The information must be recorded in the individuals' medical record. Immunization tracking systems will record the exemption code "MD" for personnel who decline anthrax vaccination.

5. Other Requirements and Provisions.

5.1. Each Military Service and affected Defense Agency shall implement operational plans, consistent with references (a) and (b) and this memorandum, to administer the vaccinations to personnel initiating or resuming the vaccination series.

5.2. Personnel on orders to the U.S. Central Command area of responsibility or Korea may begin vaccinations up to 60 days before deployment or arrival.

5.3. During the period of the EUA, the policy of continuing the vaccine dosing series of six shots plus boosters for all personnel who begin it is suspended for personnel without a continuing duty assignment associated with the heightened risk of exposure.

5.4. Previously established medical exemptions and clinical policies (except as provided in paragraph 5.3, above) remain in effect, including policies relating to vaccine-associated adverse events. The Assistant Secretary of Defense (Health Affairs) may revise or supplement clinical policies.

5.5. Previously established policies applicable to vaccinations of Reserve Component personnel, when covered under section 1, above, remain in effect.

5.6. Clinical sites authorized to provide vaccinations during the EUA period will be restricted under procedures set by the Executive Agent.

5.7. Anthrax vaccinations may be provided in other venues (e.g., embassies and missions of the Department of State), provided that the requirements in this memorandum and reference (b) are met.

5.8. A U.S. District Court injunction against mandatory vaccinations remains in effect for the present time. A copy of the Court's Order and Opinion (available at www.anthrax.mil) shall be available at every vaccination clinic for potential vaccine recipients to read. The Executive Agent shall establish verification and reporting requirements to ensure compliance with the current prohibition on mandatory vaccinations. The Court has ordered DoD to provide weekly reports to the Court regarding compliance with the prohibition on mandatory vaccinations.

5.9. Previously established management responsibilities remain in effect. The Secretary of the Army shall continue to function as Executive Agent, managing and administering the overall program and acting as focal point for the submission of information from the Services and projected vaccine program requirements. The Executive Agent shall issue operational instructions to the Services and coordinate and monitor Service implementation of the program. The Military Vaccine Agency is recognized as the operational activity of the Executive Agent.

5.10. The senior military official from each of the Services previously assigned to direct and implement their respective anthrax vaccine implementation plan shall continue in this role. As such, they will implement, monitor, evaluate and document the AVIP in their respective Services. Defense Agency AVIP officials responsible for their AVIP execution shall conform to the same standards.

5.11. The EUA is currently scheduled to expire July 27, 2005. At that time, other initiatives may result in resumption of the normal AVIP, including mandatory vaccinations for selected personnel. Alternatively, the EUA may be extended or other direction may be provided.

As directed by the Deputy Secretary, resumption of the AVIP requires scrupulous attention to the terms and conditions of the EUA. The AVIP remains a critically important component of the Force Health Protection program for the Armed Forces.

David S.C. Chu

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1, *et al*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-707 (EGS)
DONALD H. RUMSFELD, *et al*	)	
Defendants.	)	

ORDER

On October 27, 2004, this Court issued an order permanently enjoining the military's anthrax vaccine program. Specifically, the Court held, "Unless and until FDA classifies AVA as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. § 1107. Accordingly, the involuntary anthrax vaccine program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver."

Defendants have now filed an Emergency Motion to Modify the Injunction, seeking clarification that there exists a third option - an alternative to informed consent or a Presidential waiver - by which defendants can administer AVA to service members even in the absence of FDA approval of the drug: that is, pursuant to an Emergency Use Authorization ("EUA") under the

Project BioShield Act of 2004, 21 U.S.C.A. § 360bbb-3.

In enacting the EUA provision, Congress appears to have authorized the use of unapproved drugs or the unapproved use of approved drugs based on a declaration of emergency by the Secretary of Health and Human Services, which in turn is based on "a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological or nuclear agent or agents." 21 U.S.C.A. § 360bbb-3(b)(1)(B).

Without ruling on the lawfulness or merits of any EUA, upon consideration of the defendants' motion, the opposition and replies thereto, the *amicus curiae* brief, the arguments heard in open court on March 21, 2005, and the draft language jointly submitted by the parties in this case, it is hereby

ORDERED that the defendants' Motion to Modify the Injunction is **GRANTED**; it is further

ORDERED that the Court's injunction of October 27, 2004, is modified by the addition of the following language: "This injunction, however, shall not preclude defendants from administering AVA, on a voluntary basis, pursuant to the terms of a lawful emergency use authorization ("EUA") pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act, without prejudice to a future challenge to the validity of any such EUA.

The Court expressly makes no finding as to the lawfulness of any specific EUA that has been or may be approved by the Department of Health and Human Services."

Signed: Emmet G. Sullivan
United States District Judge
April 6, 2005

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 04-5440

September Term, 2005

FILED ON:

JOHN DOE,1 THROUGH 4; JANE DOE, 1 THROUGH 2; AND OTHER SIMILARLY SITUATED INDIVIDUALS,
APPELLEES

v.

DONALD H. RUMSFELD, SECRETARY OF DEFENSE, ET AL.,
APPELLANTS

Appeal from the United States District Court
for the District of Columbia
(No. 03cv00707)

Before: RANDOLPH, TATEL, and GRIFFITH, *Circuit Judges*.

JUDGMENT

This case was considered on the record from the United States District Court for the District of Columbia and on the briefs and arguments of the parties. It is

ORDERED AND ADJUDGED that the case be remanded to the district court because the appeal is moot. At issue here is—or rather, was—the validity of a permanent injunction forbidding the Department of Defense from administering anthrax vaccine adsorbed (AVA) to members of the military without their consent. By its own terms, that injunction remained in effect "[u]nless and until FDA classifies AVA as a safe and effective drug for its intended use." *Doe v. Rumsfeld*, No. 03-707 (D.D.C. Oct. 27, 2004) (order granting plaintiffs' motion for summary judgment) ("Summ. J. Order"). In its order of December 19, 2005, FDA did just that, namely, classified AVA as "safe and effective and not misbranded." Implementation of Efficacy Review; Anthrax Vaccine Adsorbed; Final Order, 70 Fed. Reg. 75,180, 75,182 (Dec. 19, 2005).

By its own terms, then, the injunction has dissolved, and this case no longer presents a live controversy on which we may pass judgment. *See Nat'l Black Police Ass'n v. District of Columbia*, 108 F.3d 346, 349 (D.C. Cir. 1997) ("a live controversy must exist at all stages of review"). Although the parties still dispute whether AVA's original 1970 license takes it outside

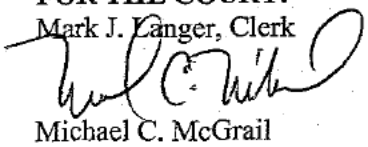
the definition of "drug unapproved for its applied use" within the meaning of 10 U.S.C. § 1107(g)(2), resolving that issue would have no practical effect on the now-dissolved injunction, and we have "no power to . . . decide questions that cannot affect the rights of litigants in the case before [us]." *Nat'l Black Police Ass'n*, 108 F.3d at 349 (internal quotation marks removed).

The government argues that the case is not moot because the district court's final order "encompasses a declaration that the vaccine's 1970 license does not extend to inhalation anthrax." Reply to Opp'n to Appellant's Mot. to Govern Further Proceedings 2. As we read the district court's order, however, it never granted such declaratory relief, nor any other relief except the injunction. *See* Summ. J. Order.

In the event we find the case moot, the government urges us to vacate the district court's opinion. We decline to do so, and instead remand with instructions to the district court to consider that request. *See U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship*, 513 U.S. 18, 29 (1994) ("a court of appeals presented with a request for vacatur of a district-court judgment may remand the case with instructions that the district court consider the request").

Pursuant to D.C. Circuit Rule 36, this disposition will not be published. The clerk is directed to withhold issuance of the mandate herein until seven days after resolution of any timely petition for rehearing or rehearing en banc. *See* Fed. R. App. P. 41(b); D.C. Cir. R. 41.

Per Curiam
FOR THE COURT:
Mark J. Langer, Clerk

BY: 
Michael C. McGrail
Deputy Clerk

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

OCT 12 2006

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

SUBJECT: Anthrax Vaccine Immunization Program

Based on the continuing heightened threat to some U.S. personnel of attack with anthrax spores, the Department of Defense will resume a mandatory Anthrax Vaccine Immunization Program, consistent with Food and Drug Administration guidelines and the best practice of medicine, for designated military personnel, emergency-essential and comparable Department of Defense civilian employees, and certain contractor personnel performing essential services. Vaccination is mandatory for these personnel based on geographic area of assignment or special mission roles, except as provided under applicable medical and administrative exemption policies.

As it was under the Deputy Secretary of Defense Memorandum of June 28, 2004, "Expansion of Force Health Protection Anthrax and Smallpox Immunization Programs for DoD Personnel," the scope of the mandatory Anthrax Vaccine Immunization Program shall encompass personnel assigned to or deployed for 15 or more consecutive days in higher-threat areas and certain other personnel with special mission roles. 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 risk of exposure to anthrax may also be included in the program. Vaccinations shall begin, to the extent feasible, up to 60 days prior to deployment or arrival in higher-threat areas.

Consistent with the FDA-approved guidelines for use of anthrax vaccine, all personnel who begin the six-dose vaccine series (unless excluded for medical reasons) will be offered all six doses and the annual booster as long as they remain members of the armed forces or maintain a civilian employee or contractor status covered by the program. For those no longer deployed to a higher threat area or no longer assigned designated special mission roles, these later vaccine doses will be on a voluntary basis. Individuals whose vaccine series was interrupted are not required to restart the vaccine series, but will proceed in accordance with appropriate medical practice.

The Under Secretary of Defense for Personnel and Readiness (USD(P&R)) shall issue implementation guidance on the medical and administrative aspects of the Anthrax Vaccine Immunization Program. Effective program implementation continues to be the responsibility of the Secretary of the Army as the Executive Agent for the Anthrax Vaccine Immunization Program and the designated senior military officers of the Services. USD(P&R) must approve Military Department and applicable Combatant Commander Anthrax Vaccine Immunization Programs prior to implementation.

Cited By (15) (/feed/search/?type=o&q=cites%3A(2378942))

This case has been cited by these op nions:

- Miller v. Holzmann (2008) (/opinion/1462112/miller-v-holzmann/?)
- Electronic Privacy Info. v. US Dept. of Homeland (2011) (/opinion/2116187/electronic-privacy- nfo-v-us-dept-of-homeland/?)
- Emp. of Bmc Software v. US SEC. of Labor (2007) (/op nion/818156/emp-of-bmc-software-v-us-sec-of-labor/?)
- Rempfer v. US DEPT. OF AIR FORCE BD. (2008) (/opinion/2297646/rempfer-v-us-dept-of-a r-force-bd/?)
- Millican v. United States (2010) (/opinion/2472676/millican-v-united-states/?)

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- Hensley v. Eckerhart, 461 U.S. 424 (1983) (/op nion/110929/hensley-v-eckerhart/?)
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- Mary Jane Ruderman H rschey v. Federal Energy Regulatory Commission, Long ... (/opinion/460996/mary-jane-ruderman-hirschey-v-federal-energy-regulatory-commission-long/?)
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Doe v. Rumsfeld, 501 F. Supp. 2d 186 (D.C. 2007)

District Court, District of Columbia

Filed: August 21st, 2007

Precedential Status: Precedential

Citations: 501 F. Supp. 2d 186

Docket Number: Civil Action No. 03-707 (EGS)

Author: Emmet G. Sullivan (/person/3133/emmet-g-sullivan/)

501 F. Supp. 2d 186 (2007)

John DOE # 1, et al., Plaintiffs,
v.
Donald H. RUMSFELD, Secretary of Defense, et al., Defendants.

Civil Action No. 03-707 (EGS).

United States District Court, District of Columbia.

August 21, 2007.

*187 Mark S. Zaid, Mark S. Zaid, P.C., Wash ngton, DC, John J. Michels, Jr., McGu re Woods, LLP, Chicago, IL, for Pla nt ffs.

Ronald James Wiltsie, Andrew H. Tannenbaum, Craig M. Blackwell, U.S. Department of Justice, Washington, DC, for Defendants.

MEMORANDUM OPINION

SULLIVAN, District Judge.

Six plaint ffs, known as John Doe # 1 through # 4 and Jane Doe # 1 and # 2, brought this action to challenge the lawfulness of the defendants' Anthrax Vaccination Immunization Program ("AVIP"). Currently pending before the Court is pla nt ffs' motion for attorneys' fees and costs. Upon consideration of the motion, the response and reply thereto, the applicable law, and the ent re record, the Court determines that pla nt ffs are entitled to attorneys' fees, but that the r pending request is flawed in several, significant aspects. Therefore, for the reasons stated here n, pla nt ffs' motion for attorneys' fees and costs is DENIED without prejudice.

BACKGROUND

This Court set forth a detailed description of the case's regulatory and procedural background in its 2004 opinion, *see Doe v. Rumsfeld,* 341 F. Supp. 2d 1 (/opinion/2459105/doe-v-rumsfeld/), 3-8 (D.D.C. 2004), so it need only be summarized here. Pursuant to a process established for drugs whose regulation was transferred from the National Institutes of Health to the FDA, the FDA issued a proposed order concerning AVA n 1985. *Id.* at 4-6. The FDA panel, whose report was incorporated into the proposed order, concluded that AVA was safe and effective "under the l mited circumstances for which it *i*s employed." *Id.* at 4-5. The panel did so after examining the "Brachman study," which investigated AVA's, effectiveness against cutaneous anthrax and nhalation anthrax. *Id.* at 5. The proposed order recommended that AVA be placed n "Category I," which encompassed drugs that are safe, effective, and not misbranded. *Id.* Pursuant to its regulations, the FDA published notice of the proposed rule and solicited comments for 90 days. *Id.* at 5-6. Following the receipt of comments, the *188 FDA took no further action until this suit was filed. *Id.* at 6.

In March 2003, pla ntiffs filed suit n this Court, alleg ng that the AVIP violated federal law because AVA had never been approved as a safe and effective drug for protection against inhalation anthrax. *Id.* On December 22, 2003, the Court issued a preliminary injunction enjo ning AVIP inoculations absent consent because the FDA had never issued a final decision regard ng the safety of AVA. *Id.* Eight days later, the FDA issued a final order classify ng AVA as a Category I drug, stating that it was effective regardless of the route of exposure. *Id.* The final order re-analyzed the data underlying the 1985 proposed order and also relied upon studies conducted after 1985. *Id.* at 7. Both parties subsequently moved for summary judgment, with pla ntiff seeking permanent njunctive relief. *Id.* at 8.

On two initial matters, the Court determined the plaintiffs had standing and that the FDA's December 2003 decision constituted an order, instead of a rule. *Id.* at 9-12. Even though the decision was an order, the Court concluded that because the FDA regulations requ red notice and comment for the order, the notice and comment must have been procedurally sufficient under the standards of the Adm nistrative Procedure Act. *Id.* at 13. Utiliz ng the logical outgrowth doctrine, the Court concluded that the notice and comment for AVA was insufficient because the final order deviated too greatly from the proposes order. *Id.* at 15. Defendants had contended that the proposed order was substantively identical to the final order because the proposed order class fied AVA as a Category I drug and did not l mit its application to any particular route of exposure. *Id.* at 14. The Court, however, found that the scope of the proposed order's recommendation did not include inhalation anthrax because the proposed order stated that there was insufficient data concern ng AVA's effectiveness against inhalation anthrax. *Id.* at 15. Therefore, the public was not on notice that AVA was being considered for use aga nst inhalation anthrax spec fically, and thus the FDA's procedure did not provide a meaningful opportunity for comment as requ red by the FDA's own regulations. *Id.* As a remedy,' the Court vacated the final order and remanded it to the FDA for reconsideration. *Id.* at 16. In addition, the Court entered a permanent injunction enjoining defendants' use of AVA absent consent until the FDA properly classified AVA as safe and effective for its intended purpose. *Id.* at 19.

While this case was on appeal, n December 2005, the FDA issued a new final order after a notice-and-comment period, explicitly find ng AVA efficacious against inhalation anthrax. *See Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed,* 70 Fed.Reg. 75,180 (Dec. 19, 2005). As a result, the D.C. C rcuit held that this Court's permanent injunction had dissolved by its own terms, dismissed the appeal as moot, and remanded the case to this Court for further proceedings. *Doe v. Rumsfeld,* 172 Fed.Appx. 327 (D.C.C r.2006) (per curiam). On remand, the only rema n ng issue is plaint ffs' motion for attorneys' fees and costs under the Equal Access to Justice Act ("EAJA"), 28 U.S.C. § 2412(d).

ANALYSIS

Plaint ffs have filed an application for $508,310.44 in attorneys' fees and costs. Defendants first contend that plaintiffs are not entitled to any fees and costs because defendants' position was substantially just fied. In the alternative, defendants contend that the proper award is much less than pla nt ffs' request because (1) plaintiffs *189 are not prevailing parties with regard to their appeal to the D.C. Circuit; (2) pla ntiffs' requested rate for their counsel is above the statutory limit; and (3) plaintiffs' purported billable hours are too high because they improperly seek re mbursement for certain activities and their billing records are too vague.

I. Substantial Justification

The EAJA provides that a prevail ng party in a non-tort suit against the United States is entitled to fees and expenses unless the government's position was "substantially just fied." 28 U.S.C. § 2412(d)(1)(A). The Supreme Court has held that a position is substantially justified " f a reasonable person could think it correct, that is, if it has a reasonable basis n law and fact." *Pierce v. Underwood,* 487 U.S. 552 (/op nion/112137/pierce-v-underwood/), 556, 108 S. Ct. 2541 (/opinion/112137/pierce-v-underwood/), 101 L. Ed. 2d 490 (/opinion/112137/pierce-v-underwood/) (1988). The D.C. C rcuit has stated that "the hallmark of the substantial justification test is reasonableness." *Role Models Am., Inc. v. Brownlee,* 353 F.3d 962, 967 (D.C.Cir.2004). The government bears the burden of establish ng that its position was substantially justified. *F.J. Vollmer Co., Inc. v. Magaw,* 102 F.3d 591 (/op nion/731217/fj-vollmer-company-inc-v-john-w-magaw-d rector-bureau-of-alcohol/), 595 (D.C.Cir.1996). Moreover, the government must demonstrate the reasonableness of both the agency's actions as well as its litigation position. *Role Models,* 353 F.3d at 967.

The question of reasonableness cannot be collapsed into the antecedent evaluation on the merits; it is a distinct legal standard. *F.J. Vollmer,* 102 F.3d at 595. The court's reasoning on the merits, however, may be quite instructive in resolving the substantial just fication issue. *Id.* For nstance, a finding on the merits that an agency's decision lacked substantial evidence generally implies that the agency's decision was unreasonable. *Id.* In addition, f an agency failed "to enforce a rule where it plainly applied," it is much more likely that the agency's decision was not substantially justified. *Id.*

Defendants contend that their position, at both the agency level and dur ng litigation, was reasonable because they reasonably construed the 1985 proposed order as encompass ng approval of AVA for treat ng nhalation anthrax. In support of this position, defendants point out that the proposed order classified AVA as a Category I drug and did not limit its approval to a particular route of exposure. If this view of the proposed' order was reasonable, then the agency's procedures would have been proper because the 2003 final order would have been the logical outgrowth of the proposed order.

In the 2004 opinion, the Court concluded that the proposed order did not encompasses approval of AVA against inhalation anthrax, especially in the context of a potential biological attack as AVA is used in the AVIP. *Doe,* 341 F.Supp.2d at 15. The Court reached this conclusion by focus ng on two key statements in the proposed order. The first is that the proposed order found AVA safe and effective for the "limited circumstances" of its usage at that time, specifically inoculating individuals n

certa n ndustrial settings who worked with animal furs and hairs. *Id.* The second is that the proposed order, in analyzing the Brachman study, found that the lack of data permitted no mean ngful analysis of file AVA's effectiveness against nhalation anthrax. *Id.* Thus, the public was not on notice that AVA would be deemed safe and effective against inhalation anthrax. *Id.*

The question of whether defendants' litigation position was substantially justified is a close one. Even conceding, that the Court's analysis was correct, defendants make the argument that the r view of the proposed order was still reasonable. They argue that because the proposed *190 order did not explicitly limit its approval of AVA to any particular route of exposure, it is at least reasonable to nterpret the proposed order as cover ng all routes of exposure. The Court, however, finds more persuasive the argument that the proposed order could not have meant to approve AVA for' nhalation anthrax when it explicitly stated that it found no evidence to prove AVA's effectiveness against inhalation anthrax. In fact, the 2003 final order had to directly contradict the scient fic conclusions in the proposed order regarding the. Brachman study in order to support the position that AVA was effective against inhalation anthrax. *See id.* at 7. Given the explicit qual fications in the proposed order and the reversal n analysis in the 2003 final order, the Court concludes that defendants' litigation position was not substantially justified under the EAJA.

In addition, for the government's position to be substantially justified, the agency's actions also must have been reasonable. *Role Models,* 353 F.3d at 967. Plaintiffs contend that the defendants' actions were clearly unreasonable when they instituted the AVIP program without any final FDA order approv ng the usage of AVA. *See Doe v. Rumsfeld,* 297 F. Supp. 2d 119 (/opinion/2326816/doe-v-rumsfeld/), 133-34 (D.D.C.2003) (concluding that AVIP program violated federal law and entering preliminary injunction because the FDA had not issued a final order and no study proved AVA's effectiveness against inhalation anthrax). Rather than appeal the Court's conclusions, the FDA abruptly altered course and issued a final order merely eight days after the Court's 2003 opinion. Such a response is indicative of the unreasonableness of the agency's initial stance. Given the unreasonableness of the agencies' initial position before the lawsuit, and their sharp changes in December 2003 issuing a final order after 18 years that contradicted the proposed order the Court concludes that the government was not substantially justified in this case.

II. Prevailing Party Status

Defendants contend that plaint ffs cannot be considered a prevail ng party with regard to the appeal to the D.C. Circuit. "Normally, a prevailing party is entitled to attorney's fees for work done on appeal." *Jean v. Nelson,* 863 F.2d 759 (/op nion/515813/marie-lucie-jean-v-alan-c-nelson/), 770 (11th Cir.1988). Some courts, though, have held that if plaintiffs "did not prevail on any legal issue or obtain any additional relief" on appeal, then pla nt ffs have not prevailed at that stage of the litigation. *Id.; see also Clark v. City of Los Angeles,* 803 F.2d 987 (/opinion/478410/ruth-clark-and-charles-e-bunker-v-city-of-los-angeles-and-the-los-angeles/), 993 (9th Cir.1986) (holding that attorney's fees should not be paid for appellate work when "noth ng associated with the appeal contributed to [the] favorable result achieved by litigation").

However, "the prevalent approach to determining whether a plaintiff is a prevailing party on appeal is to nquire whether the plaint ff has prevailed n the litigation as a whole." *Schneider v. Colegio de Abogados de Puerto Rico,* 187 F.3d 30 (/opinion/765608/robert-e-schneider-jr-v-colegio-de-abogados-de-puerto-rico-robert-e/), 48 (1st C r.1999). Thus, one court n this district has rejected the idea of "b furcat[ing] a determination of whether pla nt ffs prevailed on appeal from whether pla ntiffs prevailed at trial for purposes of determining eligibility of fees." *Dougherty v. Barry,* 820 F. Supp. 20 (/opinion/1759475/dougherty-v-barry/), 25 (D.D.C. 1993). Instead, because plaintiffs ultimately prevailed on their claims, the court found plaintiffs "eligible for the reasonable fees and costs incurred on both the trial and appellate levels, including fees and costs ncurred in defending on appeal specific issues which were ult mately decided aga nst them." *Id.* In support of this position as well is the statutory language, which speaks of awarding fees and costs to a prevail ng party n a "civil action" and does distinguish between different stages *191 of the action. *See* 28 U.S.C. § 2412(d)(1)(A); *Dougherty,* 820 F.Supp. at 25.

In this case, there is no question that plaintiffs have prevailed overall as they achieved the permanent njunctive relief that they sought. *See Role Models,* 353 F.3d at 966 (hold ng that plaintiffs prevailed where they won an njunction that forestalled an agency's action until the agency properly complied with relevant regulations). It is also clear that pla ntiffs did not receive any additional relief on appeal, or an affirmation of the r position, because the appeal was mooted by the government's actions. Therefore, the question for the Court is whether award ng fees for plaintiffs' work on appeal is "reasonable" given their overall prevail ng party status. *See Hensley v. Eckerhart,* 461 U.S. 424 (/opinion/110929/hensley-v-eckerhart/), 433, 103 S. Ct. 1933 (/op nion/110929/hensley-v-eckerhart/), 76 L. Ed. 2d 40 (/opinion/110929/hensley-v-eckerhart/) (1983) (holding that once a party is determ ned to be prevailing, a court must decide what fees are "reasonable").

The Court concludes that plaint ffs are entitled to fees and costs relating to the appeal. Plaint ffs were litigating on appeal the very same issues on which they succeeded n this Court. The reason plaintiffs did not further succeed on appeal is because defendants mooted the appeal by giving pla nt ffs the exact result they sought: revised action by the FDA. f defendants intended to accede to plaintiffs, they could have saved pla ntiffs the expense of litigat ng the appeal by simply not appealing this Court's decision. As pla nt ffs incurred additional expenses only because defendants unnecessarily pursued an appeal initially, it is reasonable that plaintiffs should be reimbursed for these expenses as they ult mately prevailed. Thus, the Court rejects defendants' argument for reducing pla nt ffs' fees.

III. Proper Rate for Attorneys and Staff

Defendants contend that plaint ffs utilize an mproperly high rate for calculating their attorneys' fees. The EAJA spec fically provides that "attorney fees shall not be awarded n excess of $125 per hour unless the court determines that an ncrease n the cost of living or a special factor, such as the limited availability of qualified attorneys for the proceedings involved, just fies a higher fee." 28 U.S.C. § 2412(d)(2)(A). Defendants contend that all attorneys should be reimbursed no more than the EAJA maximum of $125 plus a cost of living adjustment.[1] Pla ntiffs contend that their attorneys' special qualifications entitle them to higher rates for fees. Spec fically, plaintiffs rely on the their attorneys' expertise in the comb ned areas of military justice, adm nistrative law, and national security.

The Supreme Court has interpreted the EAJA's rate clause narrowly, holding, that enhanced rates are permitted only for "attorneys hav ng some distinctive knowledge or specialized skill." *Pierce,* 487 U.S. at 572, 108 S. Ct. 2541 (/opinion/112137/pierce-v-underwood/). As examples, the Court has referred to "an ident fiable practice specialty such as patent law, or knowledge of foreign law or language." *Id.* The D.C. Circuit has interpreted this to mean that fee enhancement is available only for lawyers whose specialty "requ r[es] technical or other education outside the field of American law." *Waterman Steamship Corp. v. Maritime Subsidy Bd.,* 901 F.2d *192 1119, 1124 (D.C.Cir.1990). The D.C. Circuit has also stated that expertise in adm nistrative law in a particular area, such as communications, railroads, or firearms, does not entitle attorneys to enhanced fees under the EAJA. *F.J. Vollmer,* 102 F.3d at 598-99. The Circuit has also rejected the cla m that expertise in federal election law just fies a fee enhancement. *In re Sealed Case 00-5116,* 254 F.3d 233 (/op nion/185322/in-re-sealed-case/), 236 (D.C.C r. 2001). Finally, this Court has previously rejected the assertion that expertise in Military adm nistrative law is a basis for a fee enhancement. *Lynom v. Widnall,* 222 F. Supp. 2d 1 (/opinion/2305324/lynom-v-widnall/), 6-7 (D.D.C.2002) ("Plaintiff s counsel's extensive experience n military law is simply nsufficient to warrant enhanced fees."). Therefore, the Court concludes that plaintiffs are not entitled to attorneys' fees more than the EAJA maximum of $125 plus a cost of liv ng adjustment.

Adjusting the billable rates for plaintiffs' attorneys will requ re an extensive recalculation of plaintiffs' fee request. The Court will not undertake this endeavor, but nstead will deny plaintiffs' motion for attorneys' fees without prejudice to reconsideration of an amended request n compliance with this op nion. As plaintiffs' request suffers from additional flaws, the Court will provide further guidance for plaint ffs.

Plaint ffs have also sought fees for work done by legal assistants. Pla ntiffs have the burden of justify ng the rates for which these ndividuals are billed. *Role Models,* 353 F.3d at 969-70. Pla ntiffs, however, have not submitted any information about the relevant market rate and have "not even taken the basic step of submitting an affidavit detailing the non-attorneys' experience and education." *See id.* at 970. Plaint ffs are therefore required to justify the rates for the legal assistants n their amended fee request.

IV. Proper Account ng of Billable Hours and Costs

Under this C rcuit's law, pla ntiffs have the burden of establish ng the reasonableness of the r fee request, and "support ng documentation must be of sufficient detail and probative value to enable the court to determine with a high degree of certa nty that such hours were actually and reasonably expended." *Role Models,* 353 F.3d at 970. In assessing reasonableness, prevail ng counsel "must make a good faith effort to exclude from a fee request hours that are excessive, redundant or otherwise unnecessary." *Hensley,* 461 U.S. at 434, 103 S. Ct. 1933 (/opinion/110929/hensley-v-eckerhart/). One disfavored practice is submitt ng time records that "lump together multiple tasks, making it impossible to review the r reasonableness." *Role Models,* 353 F.3d at 971. Another flaw in time records is inadequate detail, such as records that only describe work as "research," "writ ng," or "participating n teleconference." *Id.* Finally, duplication of effort is another basis on which fee requests can be deemed excessive. *Id.* at 972. Defendants contend that plaintiffs' fee request suffers from all of these problems. In addition, defendants contend that plaintiffs' requested billable hours must be reduced for a variety of spec fic reasons, each of are analyzed in turn.

A. Media Contacts

Defendants contend that 29.5 hours should deducted from plaintiffs' request because they seek re mbursement for media contacts. "In this circuit, the government cannot be charged for time spent n discussions with the press." *Role Models,* 353 F.3d at 973. Pla ntiffs concede this argument. Therefore, these hours should not be included in the amended fee request.

*193 B. Travel Time

Defendants contend that 16 hours should deducted from plaintiffs' request because they seek re mbursement for 32 hours of travel time. Travel is time is supposed to be compensated at ha f the attorney's hourly rate. *See Cooper v. U.S.R.R. Retirement Bd.,* 24 F.3d 1414 (/opinion/670646/denver-s-cooper-v-united-states-railroad-ret rement-board/), 1417 (D.C.Cir.1994). Pla nt ffs concede this argument. Therefore, these hours should not be included n the amended fee request.

C. Admission to the Court

Defendants contend that 8.7 hours should deducted from plaintiffs' request because they seek re mbursement for t me spent seeking admission to this Court. A fee request cannot include such time because this Circuit has held that "the cost of jo n ng the bar of this court [is] an expense of doing business not chargeable to clients much less to the federal government." *Role Models,* 353 F.3d at 973. Plaintiffs concede this argument. Therefore, these hours should not be included in the amended fee request.

D. Recovery for Matters Outside the Litigation

Defendants contend that plaint ffs' fee request nappropriately seeks reimbursement for matters outside this litigation. Plaintiffs are only entitled to fees and costs aris ng in this "civil action." 28 U.S.C. § 2412(d)(1). Defendants specifically challenge pla nt ffs' requests for re mbursement for (1) work on a Seventh C rcuit case, (2) work related to a separate FOIA lawsuit, and (3) work related to the notice-and-comment period that resulted in the FDA's final order n 2005. This last request relates to work that occurred after this Court's final judgment and appears more connected to pla ntiffs' separate litigation over the 2005 order. *See Doe, v. Von Eschenbach,* 06-2131-RMC (D.D.C. 2006); *see also NAACP v. Donovan,* 554 F. Supp. 715 (/op nion/1629482/naacp-v-donovan/), 720 (D.D.C.1982) (indicating that fees are not available for work related to rulemaking proceedings). Therefore, unless they provide a convincing explanation, pla ntiffs should not seek re mbursement for these matters in the amended fee request.

E. Work on an Unfiled Motion

Defendants contend that plaint ffs inappropriately seek reimbursement for work on a motion that was never filed. This motion was pla nt ffs' motion for an order to show cause why defendants should not be held n contempt for violating the Court's permanent injunction. The work on this motion, totaling 31.3 hours, occurred n February 2005, after the Court's permanent njunction was entered. Plaintiffs briefly cla m that this, work was necessary to preserve the integrity of the injunction.

Defendants argue that it is unreasonable to allow fees to be paid for this work because it may have been unnecessary. The needlessness of the work was potentially unrevealed because defendants never had the opportunity to oppose the motion. Plaintiffs have not refuted this possibility because they have not explained why the motion was necessary and yet never filed. Without such an explanation, the Court cannot fully evaluate the reasonableness of plaintiffs' request. Therefore, unless they provide a fuller explanation, pla nt ffs should not seek re mbursement for work on this motion in the amended fee request.

F. Clerical Matters

Defendants contend that plaint ffs inappropriately seek reimbursement for clerical or adm nistrative work. Purely clerical or secretarial tasks, which do not requ re the skills of an attorney or legal assistant, cannot be included n a fee petition. *See Role Models,* 353 F.3d at 973. Plaintiffs' *194 fee request includes numerous entries for updating files, download ng documents, and sending documents. Many of these tasks appear clerical or secretarial, and plaintiffs have not expla ned how the tasks requ re the skills of at least a paralegal. Therefore, unless they provide an explanation, plaintiffs should not seek reimbursement for this work in the amended fee request.

G. Attorney Zaid's Vague Entries

Defendants contend that many billing entries for attorney Mark Zaid are too vague to allow the Court to evaluate their reasonableness. The D.C. Circuit has held that billing entries describing work only as "research," "writ ng," or "participating n teleconference" are inadequately detailed for fee petition purposes. *Id.* at 971. Many of Zaid's entries describe his work only as "E-mails," "Tel. conv" or "Onl ne research." Under the C rcuit's standard, these entries are clearly too vague. One possible remedy is to reduce plaintiffs' fee by certain percentage because of the vague entries. *See id.* at 973 (allow ng reimbursement for only fifty percent of the attorney hours that plaintiff requested because of "inadequate documentation, failure to justify the number of hours sought, inconsistencies, and improper bill ng entries"). Unless these entries are more detailed n plaint ffs' amended fee request, the Court will utilize this remedy.

H. Excessive Time on Appeal

Defendants contend that plaint ffs seek excessive reimbursement for work related to the appeal. Plaintiffs reta ned twelve additional lawyers (besides the main attorneys Zaid and John Michels) to work on the appeal and, by defendants' calculation, devoted 578 hours to the appeal. Defendants argue that it was excessive to involve twelve new lawyers on the case, and that 578 hours was unnecessary as many of the legal issues nvolved had been fully researched and discussed for

proceedings in this Court. Plaintiffs briefly claim that such a large number of attorneys and hours was necessary because of the "complexity of the case and the fact that the record is so voluminous." In light of plaintiffs' perfunctory explanation, the utilization of twelve new attorneys on appeal appears unreasonably excessive. As a remedy, defendants recommend a 50% reduction in fees for the extra twelve attorneys. Unless plaintiffs' amended fee request includes a more complete explanation for the work on appeal, the Court will utilize this remedy.

I. Expenses

Defendants challenge plaintiffs' request for expenses related to its team of investigators. Plaintiffs seek $15,000 for "its team of investigators and factual researchers who assisted counsel in securing documents, analyzing the administrative record, preparing a chronology of administrative action regarding AVA and document management services." Plaintiffs identify these individuals by name, but have not supported this request with any details as to these individual's activities other than to reference the times that they appear in the attorneys' billing records. Thus, the Court has no basis for assessing the amount of time that these individuals devoted to this case, what they did, how much they were paid, and thus whether the, requested reimbursement was reasonable. Therefore, unless they provide more complete documentation, plaintiffs should not seek reimbursement for these expenses in the amended fee request.

J. Costs

Defendants contend that most of plaintiffs' requested costs cannot be reimbursed. Under the EAJA, costs are limited *195 to those "enumerated in section 1920 of this title." 28 U.S.C. § 2412(a)(1). As pertinent here, section 1920 limits recovery for costs to (1) fees of the clerk or marshal, (2) fees for transcripts, (3) fees for printing and witnesses, and (4) fees for copying. 28 U.S.C. §§ 1920(1)-(4). Plaintiffs, however, have sought costs for overhead, secretarial services, taxi fares, messenger costs, telephone bills, postage, meals, and travel, which are not compensable in this circuit. *See, e.g., Hirschey v. FERC,* 777 F.2d 1 (/opinion/460996/mary-jane-ruderman-hirschey-v-federal-energy-regulatory-commission-long/), 6 (D.C.Cir.1985) (holding that taxi fares, overhead, and secretarial services cannot be reimbursed); *Mass. Fair Share v. Law Enforcement,* 776 F.2d 1066 (/opinion/460919/massachusetts-fair-share-v-law-enforcement-assistance-administration/), 1069 (D.C.Cir.1985) (holding that travel expenses, telephone bills, and postage are not compensable under EAJA). The only properly charged costs sought by plaintiffs are fees for copying and hearing transcripts. Thus, plaintiffs' amended request for costs should be limited to only those costs.

CONCLUSION

The Court concludes that plaintiffs are entitled to fees and costs for litigating this action, including on appeal, because plaintiffs are the prevailing party and the government's position was not substantially justified. Plaintiffs' request for attorneys' fees and costs, however, contains flaws that preclude the Court from determining the proper amount of fees and costs in this case. Therefore, plaintiffs' motion for attorneys' fees is DENIED without prejudice to reconsideration of an amended request in compliance with this opinion. Plaintiffs are directed to file an amended motion for attorneys' fees in light of this opinion by no later than September 28, 2007. In the alternative, if the parties seek to negotiate a fee award, the parties shall file a joint status report and recommendation for future proceedings by no later than September 28, 2007. An appropriate Order accompanies this Memorandum Opinion.

NOTES

[1] Defendants calculated the cost of living increase by using the Consumer Price Index for all Urban consumers. *See Role Models,* 353 F.3d at 969. Using this method, the maximum rate allowed for each year is $138.25 for 2000, $142.18 for 2001, $144.43 for 2002, $147.72 for 2003, $151.65 for 2004, $156.79 for 2005, and $161.05 for 2006. Defs.' Opp. at 19 n. 6.

DEPARTMENT OF THE NAVY
BOARD FOR CORRECTION OF NAVAL RECORDS
701 S. COURTHOUSE ROAD, SUITE 1001
ARLINGTON, VA 22204-2490

5448-14/
8917-13
TJR
Docket No: [redacted]

17 June 2014

From: Chairman, Board for Correction of Naval Records
To: Secretary of the Navy

Subj: REVIEW NAVAL RECORD OF [redacted]

Ref: (a) 10 U.S.C. 1552
(b) HQMC MMMA-3 memo dated 10MAR14

Encl: (1) DD Form 149 with attachments
(2) Case summary
(3) Subject's service record/CD

1. Pursuant to the provisions of reference (a), Petitioner, a former member of the Marine Corps, filed enclosure (1) with this Board requesting that recharacterization of his general discharge and a change of his narrative reason for separation (court-martial). By implication, he requested that his separation code (SPD) of JJD2 also be changed. He further requests to have his record reflect his entitlement to a Global War on Terrorism Expeditionary Medal (GWTEM) for his service in Bahrain.

2. The Board, consisting of Mr. Bey, Mr. Hedrick, and Ms. Wilcher reviewed Petitioner's allegations of error and injustice on 10 June 2014 and, pursuant to its regulations, determined that the partial corrective action indicated below should be taken on the available evidence of record. Documentary material considered by the Board consisted of the enclosures, naval records, and applicable statutes, regulations, and policies. In addition the Board considered the advisory opinion (AO), reference (b), provided by the Headquarters Marine Corps Military Awards Branch (MMMA-3).

3. The Board, having reviewed all the facts of record pertaining to Petitioner's allegations of error and injustice finds as follows:

a. Before applying to this Board, Petitioner exhausted all administrative remedies available under existing law and regulations within the Department of the Navy.

b. Enclosure (1) was filed in a timely manner.

c. Petitioner served in the Marine Corps from 27 October 1997 until 10 August 2005. During his period of service, he was

convicted by special court-martial (SPCM) of a 21 day period of unauthorized absence (UA) and disobedience. He was sentenced to a reduction to paygrade E-1 and a bad conduct discharge (BCD). He was issued the BCD on 10 August 2005.

d. On 11 January 2012 the Naval Discharge Review Board (NDRB) upgraded Petitioner's characterization of service to general under honorable conditions, based in part, on the severity of the SPCM sentence and his good post service conduct. However, it appears that the narrative reason for separation and separation code were not changed to coincide with the recharacterization of service. Presumably, because of this administrative oversight, the narrative reason for separation on his re-issued Certificate of Release or Discharge from Active Duty (DD Form 214) remains as "court-martial" instead of Secretarial Authority. Further, his SPD should be LFF1 (Secretarial Authority).

e. In regard to Petitioner's request for correction of his record to reflect a GWTEM, the AO from HQMC MMMA-3, reference (b), validates his entitlement to this award for his service in Bahrain, and as such the record should be corrected.

f. In Petitioner's application he asserts, in part, that his discharge was too harsh because it was based solely on one isolated incident, which was the result of stress, depression, and family problems. He also states that he was lied to regarding his reenlistment and career in the Marine Corps and that because of the foregoing, his discharge should be upgraded to honorable.

CONCLUSION:

Upon review and consideration of all the evidence of record, the Board concludes that Petitioner's request warrants partial favorable action.

The Board is aware of Petitioner's BCD which was awarded at his SPCM and does not condone his misconduct. However, the Board is also aware of the NDRB decision to upgrade the BCD to general under honorable conditions. In this regard, the Board's decision to change the narrative reason for separation is based on the NDRB decision to upgrade the characterization of service and its administrative oversight not to change the reason for separation, Petitioner's overall record of satisfactory service, and his good post service conduct. As such, the Board concludes that no useful purpose is served by Petitioner's record continuing to reflect such a stigmatizing narrative reason for separation and that a change of this reason to Secretarial Authority, to coincide with the NDRB decision, is now more appropriate. The Board also concludes that his SPD should be changed to LFF1 and he should be entitled to wear the GWTEM.

The Board, however, does not believe that any further recharacterization of Petitioner's service is appropriate or warranted. In view of the foregoing, the Board finds the existence of an injustice warranting the following partial corrective action.

RECOMMENDATION:

a. That Petitioner's naval record be corrected to reflect that he was discharged by reason of "Secretarial Authority" and assigned a separation code of "LFF1" on 10 August 2005 vice being discharged by reason of court-martial with a separation code of JJD2.

b. That Petitioner's naval record be corrected to reflect, in Block 13. of his DD Form 214, the GWTEM.

c. That no further relief be granted.

d. That a copy of this Report of Proceedings be filed in Petitioner's naval record.

e. That, upon request, the Department of Veterans Affairs be informed that Petitioner's application was received by the Board on 31 March 2014.

4. Pursuant to Section 6(c) of the revised Procedures of the Board for Correction of Naval Records (32 Code of Federal Regulations, Section 723.6(c), it is certified that a quorum was present at the Board's review and deliberations, and that the foregoing is a true and complete record of the Board's proceedings in the above entitled matter.

ROBERT D. ZSALMAN
Recorder

BRIAN J. GEORGE
Acting Recorder

5. Pursuant to the delegation of authority set out in Section 6(e) of the revised Procedures of the Board for Correction of Naval Records (32 Code of Federal Regulation, Section 723.6(e)) and having assured compliance with its provisions, it is hereby announced that the foregoing corrective action, taken under the authority of reference (a), has been approved by the Board on behalf of the Secretary of the Navy.

ROBERT D. ZSALMAN
Acting Executive Director

CRS
Docket No: 7959-05
23 February 2006

From: Chairman, Board for Correction of Naval Records
To: Secretary of the Navy

Subj: REVIEW OF NAVAL RECORD

Ref: (a) Title 10 U.S.C. 1552
(b) SECNAVINST 1910.4B

Encl; (1) DD Form 149 w/attachrnents
(2) Case Summary
(3) Subject's naval record

1. Pursuant to the provisions of reference (a), Petitioner, a former enlisted member of the Navy, filed enclosure (1) with this Board requesting, in effect, that his naval record be corrected to show a more favorable type of discharge and reason for discharge than the general discharge by reason of misconduct issued on 25 November 1998. Additionally, he requests that his reentry code of RE-4 be changed and that his records be corrected to show that he was a seaman (SN; E-3) at the time of discharge.

2 The Board, consisting of Messrs and reviewed Petitioner's allegations of error and injustice on 23 February 2006 and, pursuant to its regulations, determined that the corrective action indicated below should be taken on the available evidence of record. Documentary material considered by the Board consisted of the enclosures, naval records, and applicable statutes, regulations and policies.

3. The Board, having reviewed all the facts of record pertaining to Petitioner's allegations of error and injustice, finds as follows:

a. Before applying to this Board, Petitioner exhausted all administrative remedies available under existing law and regulations within the Department of the Navy.

b. Although it appears that Petitioner's application was not filed in a timely manner, it is in the interest of justice to waive the statute of limitations and review the application on its merits.

c. Petitioner enlisted in the Navy on 30 January 1996. He then served for more than two years without incident, advancing in rate to petty officer third class (0S3; E-4).

d. The record reflects that on 3 July 1998 Petitioner received nonjudicjal punishment (NJP) for disobeying a lawful command from a

superior commissioned officer. The record provides no details concerning the order that Petitioner disobeyed. The punishment imposed consisted of a forfeiture of $568 per month for two months, restriction and extra duty for 60 days, and reduction in rate from OS3 to SN.

e. On 3 September 1998 Petitioner received a second NJP for failure to go to his appointed place of duty to receive an anthrax vaccination. His medical record reflects that on 1 November 1998 Petitioner refused to receive an anthrax vaccination. On 2 November 1998 Petitioner received a third NJP for willfully disobeying a superior commissioned officer. On 9 November 1998 the commanding officer set aside the last two NJPs for unknown reasons.

f. On 11 November 1998, after Petitioner was advised of administrative separation action and waived his right to an administrative discharge board, his commanding officer (CO) recommended that Petitioner be separated with a general discharge by reason of misconduct due to commission of a serious offense. In making the recommendation, the CO referenced the NJP of 3 July 1998, and stated that Petitioner was incapable of adhering to the rules and regulations of the Navy and his command. He stated that Petitioner was simply unwilling to conduct himself in a manner conducive to good order and discipline. The discharge authority approved the separation and directed a general discharge by reason of misconduct. Petitioner was so discharged on 25 November 1998 as an SN. At that time, Petitioner was assigned a reenlistment code of RE-4.

h. Reference (b) states that an individual may be separated by reason of best interest of the service if separation is appropriate but no other reason set forth in the reference covers the situation at hand. An RE-l reenlistment code may be assigned if an individual is separated for this reason.

CONCLUSION:

Upon review and consideration of all the evidence of record the Board concludes that Petitioner's request warrants favorable action. The Board's decision to grant Petitioner's request is based on its acceptance of his contention that all of his NJPs were related to his refusal to received a vaccination against anthrax.

RECOMMENDATION.

a. That Petitioner's naval record be corrected to show that he was issued an honorable discharge by reason of best interest of the service on 25 November 1998 and a reenlistment code of RE-i, vice the general discharge by reason of misconduct and a reenlistment code of RE-4 actually issued on that date.

b. That any material or entries inconsistent with or relating to the Board's recommendation be corrected, removed or completely expunged from Petitioner's record and that no such entries or material be added to the record in the future.

c. That any material directed to be removed from Petitioner's naval record be returned to the Board, together with a copy of this Report of Proceedings, for retention in a confidential file maintained for such purpose, with no cross reference being made a part of Petitioner's naval record.

4. It is certified that a quorum was present at the Board's review and deliberations, and that the foregoing is a true and complete record of the Board's proceedings in the above entitled matter.

ROBERT D. ZSALMAN
Recorder

ALAN E. GOLDSMITH
Acting Recorder

5. Pursuant to the delegation of authority set out in Section 6(e) of the revised Procedures of the Board for Correction of Naval Records (32 Code of Federal Regulations, Section 72 3.6(e)) and having assured compliance with its provisions, it is hereby announced that the foregoing corrective action, taken under the authority of reference (a), has been approved by the Board on behalf of the Secretary of the Navy.

ex-, USMC

Current Discharge and Applicant's Request

Application Received: 20090210
Characterization of Service Received:
Narrative Reason for Discharge: FAILURE TO PARTICIPATE
Authority for Discharge: MARCORSEPMAN

Applicant's Request: Characterization change to:
Narrative Reason change to: MEDICAL/PTSD

Summary of Service

Prior Service:
Inactive: NONE Active:

Period of Service Under Review:
Date of Enlistment: 20010924 Age at Enlistment:
Period of Enlistment: Years
Date of Discharge: 20050413 Highest Rank:
Length of Service:
Active: Year(s) Month(s) 28 Day(s)
Inactive: Year(s) Month(s) 11 Day(s)
Education Level: AFQT: 50
MOS: 0311
Proficiency/Conduct Marks (# of occasions): () / () Fitness Reports:

Awards and Decorations (per DD 214): Rifle AFRM

Periods of UA/CONF:

SCM: SPCM: CC: Retention Warning Counseling:

NJP:
- 20040306: Article 92 (Disobeyed lawful order - refusing Anthrax shot)
Awarded: Suspended:

Types of Documents Submitted/reviewed

Related to Military Service:
DD 214: Service/Medical Record: Other Records:

Related to Post-Service Period:
Employment: Finances: Education/Training:
Health/Medical Records: Substance Abuse: Criminal Records:
Family/Personal Status: Community Service: References:
Additional Statements:
From Applicant: From Representation: From Congress member:

Other Documentation:

Pertinent Regulation/Law

A. Paragraph 6213 of the Marine Corps Separation and Retirement Manual, (MCO P1900.16E), effective 1 September 2001 until Present.

B. Marine Corps Reserve Administrative Management Manual, MCO P1001R.1, Chapter 3, Reserve Participation and Administrative Procedures, paragraph 3300.

C. Table 6-1 of the Marine Corps Separation and Retirement Manual, (MCO P1900.16F), effective 1 September 2001, Guide for Characterization of Service.

D. Secretary of the Navy Instruction 5420.174D of 22 December 2004, Naval Discharge Review Board (NDRB) Procedures and Standards, Part II, Para 211, Regularity of Government Affairs, Part V, Para 502, Propriety and Para 503, Equity.

DEPARTMENT OF THE NAVY
NAVAL DISCHARGE REVIEW BOARD (NDRB)
DISCHARGE REVIEW DECISIONAL DOCUMENT

Applicant's Issues

1. (Decisional) Equity of discharge due to refusing to take Anthrax vaccination.
2. (Decisional) Applicant wants narrative reason for discharge changed due to post-service diagnosis of PTSD.

Decision

Date: 20090924 Location: Washington D.C. Representation:

By a vote of the Characterization shall .
By a vote of the Narrative Reason shall SECRETARIAL AUTHORITY.

Discussion

The NDRB, under its responsibility to examine the propriety and equity of an Applicant's discharge, is authorized to change the character of service and the reason for discharge if such change is warranted. In reviewing discharges, the Board presumes regularity in the conduct of Government affairs unless there is substantial credible evidence to rebut the presumption, to include evidence submitted by the Applicant. The Applicant's record of service reflects, one Non-judicial Punishment (NJP) for violation of the Uniform Code of Military Justice (UCMJ), Article 92 (Disobeyed a lawful order – refused Anthrax shot.) Following his NJP, the Applicant refused to actively drill with his reserve unit to avoid future vaccinations. He missed a total of 12 scheduled drills. Based on these offenses, his command administratively processed him for separation. Despite having a letter hand-delivered to his home and his unit leaving a message on his answering machine to contact them, the Applicant refused to acknowledge his administrative separation processing package. The command did not refer the Applicant for a court-martial but opted instead for an administrative discharge.

: (Decisional) () . The Applicant contends he is entitled to a discharge upgrade due to his in-service record, excluding his refusal to take the Anthrax vaccination. In reviewing discharges, the Board presumes regularity in the conduct of Government affairs unless there is substantial credible evidence to rebut the presumption, to include evidence submitted by the Applicant. The Applicant's record of service reflects one NJP for violations of the Uniform Code of Military Justice (UCMJ): Article 92 (Disobeying a lawful order – refusing Anthrax shot). Violation of Article 92 (Disobeying a lawful order) is considered a serious offense which could have resulted in a punitive discharge and confinement if adjudicated and awarded as part of a sentence by a special or general court-martial. The Applicant completed two periods of active duty (to include a tour in Iraq) and attended every drill period prior to his NJP, which was his only disciplinary action. He earned average PRO/CON marks of 4.3 / 4.3 respectively. At the time of the Applicant's administrative discharge, per Chief of Naval Operations (CNO) message DTG 091306ZJAN2004, all naval personnel were required to be inoculated with the Anthrax vaccine. A subsequent CNO message DTG 290118ZOCT2004 suspended the administering of Anthrax immunizations until further notice. Since the regulation had been relaxed since the Applicant's NJP, the NDRB determined that relief was in order, and grants an upgrade in the Applicant's characterization to Honorable conditions based on his record of service.

: (Decisional)) . The Applicant states he requests an upgrade to get medical benefits due to being diagnosed with Post-traumatic Stress Disorder (PTSD), but does not state the specific details of his needs. The Applicant did provide documentation (VA file Number 384 84 8609) stating that he is receiving 50 percent disability for PTSD as of 26 February 2008. In the Applicant's personal statement, he clearly notes that he did not drill (and was subsequently discharged) because he did not want another cyst to form on his arm as a result of the Anthrax shot. He provides no proof his discharge should be based on PTSD, vice refusal to drill. The NDRB determined an upgrade based on PTSD would be inappropriate. However, since his discharge was a direct result of his refusal to drill because of mandated Anthrax shots, an order which was later

rescinded, the Board determined it would be appropriate to change his Narrative Reason to SECRETARIAL AUTHORITY.

Summary: After a thorough review of the available evidence, to include the Applicant's summary of service, service record entries, discharge process and evidence submitted by the Applicant, the Board found Therefore, the awarded characterization of service shall change to Honorable, and the narrative reason to SECRETARIAL AUTHORITY.

ADDENDUM: Information for the Applicant

Complaint Procedures: If you believe that the decision in your case is unclear, not responsive to the issues you raised, or does not otherwise comport with the decisional document requirements of DoD Instruction 1332.28, you may submit a complaint in accordance with Enclosure (5) of that Instruction to the Joint Service Review Activity, OUSD (P&R) PI-LP, The Pentagon, Washington, DC 20301-4000. You should read Enclosure (5) of the Instruction before submitting such a complaint. The complaint procedure does not permit a challenge of the merits of the decision; it is designed solely to ensure that the decisional documents meet applicable requirements for clarity and responsiveness. You may view DoD Instruction 1332.28 and other Decisional Documents by going online at "http://Boards.law.af mil."

Additional Reviews: Subsequent to a document review, former members are eligible for a personal appearance hearing, provided the application is received at the NDRB within 15 years from the date of discharge. The Applicant can provide documentation to support any claims of post-service accomplishments or any additional evidence related to this discharge. Representation at a personal appearance hearing is recommended but not required. If a former member has been discharged for more than 15 years, has already been granted a personal appearance hearing or has otherwise exhausted his opportunities before the NDRB, the Applicant may petition the Board for Correction of Naval Records (BCNR), 2 Navy Annex, Washington, DC 20370-5100 for further review.

Service Benefits: The Veterans Administration determines eligibility for post-service benefits, not the Naval Discharge Review Board. There is no requirement or law that grants recharacterization solely on the issue of obtaining Veterans' benefits and this issue does not serve to provide a foundation upon which the Board can grant relief.

Employment/Educational Opportunities: The NDRB has no authority to upgrade a discharge for the sole purpose of enhancing employment or educational opportunities. Regulations limit the NDRB's review to a determination of the propriety and equity of the discharge.

Reenlistment/RE-code: Since the NDRB has no jurisdiction over reenlistment, reentry, or reinstatement into the Navy, Marine Corps, or any other of the Armed Forces, the NDRB is not authorized to change a reenlistment code. Only the Board for Correction of Naval Records (BCNR) can make changes to reenlistment codes. Additionally, the NDRB has no authority to upgrade a discharge for the sole purpose of enhancing reenlistment opportunities. An unfavorable "RE" code is, in itself, not a bar to reenlistment. A request for a waiver can be submitted during the processing of a formal application for reenlistment through a recruiter.

Medical Conditions and Misconduct: DoD disability regulations do not preclude a disciplinary separation. Appropriate regulations stipulate that separations for misconduct take precedence over potential separations for other reasons. Whenever a member is being processed through the Physical Evaluation Board, and subsequently is processed for an administrative involuntary separation or is referred to a court-martial for misconduct, the disability evaluation is suspended. The Physical Evaluation Board case remains in suspense pending the outcome of the non-disability proceedings. If the action includes either a punitive or administrative discharge for misconduct, the medical board report is filed in the member's terminated health record. Additionally, the NDRB does not have the authority to change a narrative reason for separation to one indicating a medical disability or other medical related reasons." Only the Board for Correction of Naval Records can grant this type of narrative reason change.

Automatic Upgrades - There is no law or regulation, which provides that an unfavorable discharge may be upgraded based solely on the passage of time or good conduct in civilian life subsequent to leaving Naval service. The NDRB is authorized to consider post-service factors in the recharacterization of a discharge to the extent such matters provide a basis for a more thorough understanding of the Applicant's performance and conduct during the period of service under review. Examples of documentation that may be provided to the Board include proof of educational pursuits, verifiable employment records, documentation of community service, credible evidence of a substance free lifestyle and certification of non-involvement with civil authorities.

Issues Concerning Bad-Conduct Discharges (BCD) – Because relevant and material facts stated in a court-martial specification are presumed by the NDRB to be established facts, issues relating to the Applicant's innocence of charges for which he was found guilty cannot form a basis for relief. With respect to a discharge adjudged by a special court-martial, the action of the NDRB is restricted to upgrades based on clemency. Clemency is an act of leniency that reduces the severity of the punishment imposed. The NDRB does not have the jurisdictional authority to review a discharge or dismissal resulting from a general court-martial.

Board Membership: The names and votes of the members of the NDRB Board are recorded on the original of this document and may be obtained from the service records by writing to:

Secretary of the Navy Council of Review Boards
Attn: Naval Discharge Review Board
720 Kennon Street SE Rm 309
Washington Navy Yard DC 20374-5023

ex-CTR3, USN

Current Discharge and Applicant's Request

Application Received: 20070717
Characterization of Service Received:
Narrative Reason for Discharge:
Authority for Discharge: MILPERSMAN (SERIOUS OFFENSE)

Applicant's Request: Characterization change to:
Narrative Reason change to:

Summary of Service

Prior Service:
Inactive: USNR (DEP) 19930505 - 19930906 Active: 19930907 – 19970514 Honorable Discharge

Period of Service Under Review:
Date of Enlistment: 19970515 Period of enlistment: Years Extension Date of Discharge: 20000512
Length of Service: Yrs Mths 28 Dys Education Level: Age at Enlistment: AFQT: 89
Highest Rank/Rate: CTR2 Evaluation marks: Performance: 3.8(5) Behavior: 3.4(5) OTA: 3.52
Awards and Decorations (per DD 214): Pistol NEM (2) NAM AFOUA (3) (2)

Periods of UA/CONF:

NJPs:
20000216: Art(s) 92 (Failure to obey an order).
Awarded - Susp - Appealed 20000222. Appeal denied 20000228.

Retention Warnings: .
20000123: For failure to report to the Naval Station, Rota Spain Hospital to begin the required Anthrax Vaccination program.

20000413: For failure to begin the required Anthrax Vaccination program.

Types of Documents Submitted/reviewed

Related to Military Service: DD 214: Service and/or Medical Record: Other Records:

Related to Post-Service Period:
Employment: Finances: Education/Training:
Health/Medical Records: Substance Abuse: Criminal Records:
Family/Personal Status: Community Service: References:

Additional Statements From Applicant: From Representation: From Member of Congress:
Other Documentation (Describe)

NDRB Documentary Review Conducted (date): 20031205
NDRB Documentary Review Docket Number: ND03-00327
NDRB Documentary Review Findings: No change warranted.

DEPARTMENT OF THE NAVY
NAVAL DISCHARGE REVIEW BOARD (NDRB)
DISCHARGE REVIEW DECISIONAL DOCUMENT

Applicant's Issues

1. The Applicant contends his discharge was inequitable and was unlawful because it was based solely upon his refusal to be injected with the anthrax vaccine.
2. The Applicant is claiming in service equity based on his overall good service record.
3. The Applicant claims he has a strong post service record and is requesting an upgrade based on post service conduct.

Decision

Date: 20080627 Location: Washington D.C Representation:

By a vote of the Characterization shall .
By a vote of the Narrative Reason shall SECRETARIAL AUTHORITY.

Discussion

Issue 1 (): . The Applicant contends his discharge was inequitable and was unlawful because it was based solely upon his refusal to be injected with the anthrax vaccine. In reviewing discharges, the Board presumes regularity in the conduct of Government affairs unless there is substantial credible evidence to rebut the presumption, to include evidence submitted by the Applicant. Under applicable regulations, a discharge shall be deemed equitable unless it is determined policies and procedures used during the discharge differ in material respects from policies and procedures currently applicable on a service-wide basis: provided the current policies and procedures represent a substantial enhancement of rights afforded to the Applicant and, there is substantial doubt the Applicant would have received the same discharge if current policies and procedures had been available to the Applicant at the time of the discharge.

The Applicant was discharged on 12 May 2000 for misconduct due to commission of a serious offense, violation of Article 92 of the Uniform Code of Military Justice for failing to carry out an order to receive a series of Anthrax inoculations. On 22 December 2003, United States District Court issued an injunction enjoining anthrax inoculation in the absence of informed consent or a Presidential waiver. The Court was persuaded the anthrax vaccine was an investigational drug being used for an unapproved purpose. On 27 October 2004 the injunction was modified by the addition of the following language: "This injunction, however, shall not preclude defendants from administering anthrax, on a voluntary basis pursuant to the terms of a lawful emergency use authorization". Accordingly, the Court held the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver.

On 12 March 2007 the Chief of Naval Operations (CNO) issued guidance resuming the Mandatory Anthrax Vaccine Immunization Program for certain personnel unless exempted under applicable medical and administrative exemption policies. After reviewing personnel required to receive the mandatory Anthrax vaccine, it was noted the Applicant would not have been required to take the vaccine had he been still on active duty and assigned to the same unit prior to his discharge. Because the new anthrax guidance represents a change in policy since the Applicant's period of service, the Board determined the Applicant's discharge was inequitable in light of the DOD's action in only mandating inoculations for certain personnel in designated areas and units. The Board determined relief was warranted.

Issue 2 (): . The Applicant is claiming in service equity based on his overall good service record. A review of the Applicant's service record indicates the Applicant had only one adverse action in his record; the non-judicial punishment for refusal to submit to anthrax vaccination. Based on the U.S. District Court ruling of 27 October 2004, which issued an injunction prohibiting the Department of Defense from involuntarily requiring service members to be vaccinated, the Applicant deserves relief on the basis of his overall good service record. The Board determined relief warranted.

Issue 3 (): . The Applicant claims he has a strong post service record and is requesting an upgrade based on his post service accomplishments. Additionally, after consideration of the Applicant's substantial post service accomplishments to include receiving his bachelor's degree, his work with Habitat for Humanity, and his most recent reenlistment and honorable discharge from the naval reserves, the Board determined relief was warranted based on post service conduct. The Board determined relief was warranted.

After a thorough review of the available evidence, to include the Applicant's Summary of Service, Medical and Service Record Entries, Discharge Process and evidence submitted by the Applicant, the Board found the discharge was proper but inequitable based on current anthrax policies and regulations.

The Board voted 4 to 1 to change the discharge characterization to Honorable with the narrative reason changed to Secretarial Authority.

Dissenting Opinion

In this case, there were several issues (both listed and inferred from the Applicant's testimony) the Applicant brought before the Board:

1. The order was unlawful at the time it was given. The Applicant made this claim and references a subsequent court decisions (*Doe v. Rumsfeld*, D.D.C. Oct. 27, 2004) in support. This Court found the vaccination program to be unlawful and issued an injunction.

The minority disagrees the program was unlawful. "Military orders are presumed to be lawful and are disobeyed at the subordinate's peril." *United States v Schwartz*, 61 M.J. 567, 569 (N.M.Ct.Crim.App 2005) *affirmed* 64 M.J. 199 (C.A.A.F. 2006). Thus, the military can order service members to receive vaccinations, even over religious objections. Id. In fact, even U.S. citizens do not have the constitutional right to refuse inoculation. J*acobson v. Massachusetts*, 197 U.S. 11, 31-32 (1905). Recently, the highest court in the Armed Forces affirmed the conviction of Marine Lance Corporal Schwartz because he violated a lawful order by refusing to receive his anthrax vaccine. *See Schwartz*, 61 M.J. at 567.

In *Schwartz*, Lance Corporal Schwartz alleged the order to receive the vaccine violated his constitutional right to refuse unwanted medical treatment and he could not be inoculated with what he described as an investigational new drug without his consent. Id. at 570. The court dismissed this argument, finding the order to receive the anthrax shot was lawful because it had a valid military purpose of retaining military readiness in the face of a biological attack. Id. Regarding the issue of whether the Anthrax inoculation was merely experimental, the court noted "[i]f we may attach any value whatever to medical knowledge which is common to all civilized peoples, we must conclude on the basis of common knowledge that an order to take immunization shots is legal and necessary in order to protect the health and welfare of the military community and that failure to take such shots would represent a substantial threat to public health and safety in the military." Id. (quoting *United States v. Chadwell*, 36 C.M.R. 741, 749-50 (N.B.R. 1965).

While in service, the Applicant was given an order he should have presumed to be lawful. By choosing to disobey this order, he detracted from the good order and discipline of the United States Navy.

2. The Board is compelled to rule similarly on cases with similar circumstances. The Applicant pulled a case from the NDRB Electronic Reading Room with circumstances similar to his own in which the NDRB chose to upgrade the discharge. The minority does not find this to be a persuasive argument as each case is determined individually on its own merits.

3. Post Service Conduct. The Applicant brought evidence of several post-service accomplishments to the Board to include evidence of a successful enlistment with the Naval Reserve, completion of a Bachelor of Science program, and gainful employment with several airlines. While these are significant accomplishments, they are not sufficient in the minority's opinion to mitigate his willful disobedience of a lawful order.

4. Propriety. The applicant contends his discharge was improper because the specific circumstances of the offense did not warrant separation. The minority determined the Applicant willfully disobeyed a lawful order which is punishable by a punitive discharge and imprisonment if adjudged ad a Special or General Court Martial. The minority determined the discharge was proper.

5. Equity. The applicant feels his discharge was inequitable in light of his Record of Service. While he may feel this was the case, the minority noted the Applicant's discharge was marred by his willful disobedience of a lawful order. Such disobedience is contrary to the good order and discipline of the United States Navy and warrants a General (under honorable conditions) characterization of discharge.

6. Equity. While not brought forward as an issue by the Applicant, the Board can consider equity based on regulation currently in place. In this case, the minority believes this majority was swayed primarily by this issue. The Anthrax vaccination program has been surrounded by controversy since its inception, and the requirements for individuals to participate in the program have changed several times. While it is true the Applicant would likely not be required to take the vaccination series if he were in the Navy today, the minority notes he was required to take it at the time of his discharge, and at that time, it was a lawful requirement. Servicemen and women can not pick and choose which orders they choose to follow, and when they do, they break down the discipline and morale of a command. The minority believes this issue is not applicable because even by today's standards, a service member can be ordered to receive the Anthrax series of vaccinations. The minority finds the discharge was equitable.

In summary, the minority found no argument which mitigated the Applicant's decision to willfully disobey a lawful order and found the discharge to be proper and equitable.

Pertinent Regulation/Law

A. Naval Military Personnel Manual, (NAVPERS 15560C), Change 28, effective 30 March 2000 until 29 August 2000, Article 1910-142, Separation By Reason Of Misconduct - Commission of a Serious Offense.

B. Secretary of the Navy Instruction 5420.174D of 22 December 2004, Naval Discharge Review Board (NDRB) Procedures and Standards, Part II, Para 211, Regularity of Government Affairs, Part V, Para 502, Propriety and Para 503, Equity.

C. Chief of Naval Operations message of 121652ZMAR07, Resumption of Mandatory Anthrax Vaccine Immunization Program.

C. The Manual for Courts-Martial authorizes the award of a punitive discharge if adjudged as part of the sentence upon conviction

by a special or general court-martial for violation of the UCMJ, Article 92.

ADDENDUM: Information for the Applicant

Complaint Procedures: If you believe that the decision in your case is unclear, not responsive to the issues you raised, or does not otherwise comport with the decisional document requirements of DoD Instruction 1332.28, you may submit a complaint in accordance with Enclosure (5) of that Instruction to the Joint Service Review Activity, OUSD (P&R) PI-LP, The Pentagon, Washington, DC 20301-4000. You should read Enclosure (5) of the Instruction before submitting such a complaint. The complaint procedure does not permit a challenge of the merits of the decision; it is designed solely to ensure that the decisional documents meet applicable requirements for clarity and responsiveness. You may view DoD Instruction 1332.28 and other Decisional Documents by going online at "http://Boards.law.af.mil."

Additional Reviews: Subsequent to a document review, former members are eligible for a personal appearance hearing, provided the application is received at the NDRB within 15 years from the date of discharge. The Applicant can provide documentation to support any claims of post-service accomplishments or any additional evidence related to this discharge. Representation at a personal appearance hearing is recommended but not required. If a former member has been discharged for more than 15 years, has already been granted a personal appearance hearing or has otherwise exhausted his opportunities before the NDRB, the Applicant may petition the Board for Correction of Naval Records (BCNR), 2 Navy Annex, Washington, DC 20370-5100 for further review.

Service Benefits: The Veterans Administration determines eligibility for post-service benefits, not the Naval Discharge Review Board. There is no requirement or law that grants recharacterization solely on the issue of obtaining Veterans' benefits and this issue does not serve to provide a foundation upon which the Board can grant relief.

Employment/Educational Opportunities: The Board has no authority to upgrade a discharge for the sole purpose of enhancing employment or educational opportunities. Regulations limit the Board's review to a determination of the propriety and equity of the discharge.

Reenlistment/RE-code: Since the NDRB has no jurisdiction over reenlistment, reentry, or reinstatement into the Navy, Marine Corps, or any other of the Armed Forces, the NDRB is not authorized to change a reenlistment code. Only the Board for Correction of Naval Records (BCNR) can make changes to reenlistment codes. Additionally, the Board has no authority to upgrade a discharge for the sole purpose of enhancing reenlistment opportunities. An unfavorable "RE" code is, in itself, not a bar to reenlistment. A request for a waiver can be submitted during the processing of a formal application for reenlistment through a recruiter.

Medical Conditions and Misconduct: DoD disability regulations do not preclude a disciplinary separation. Appropriate regulations stipulate that separations for misconduct take precedence over potential separations for other reasons. Whenever a member is being processed through the Physical Evaluation Board, and subsequently is processed for an administrative involuntary separation for misconduct, the disability evaluation is suspended. The Physical Evaluation Board case remains in suspense pending the outcome of the non-disability proceedings. If the action includes either a punitive or administrative discharge for misconduct, the medical board report is filed in the member's terminated health record. Additionally, the NDRB does not have the authority to change a narrative reason for separation to one indicating a medical disability or other medical related reasons. Only the Board for Correction of Naval Records can grant this type of narrative reason change.

Automatic Upgrades - There is no law or regulation, which provides that an unfavorable discharge may be upgraded based solely on the passage of time or good conduct in civilian life subsequent to leaving Naval service. The NDRB is authorized to consider post-service factors in the recharacterization of a discharge to the extent such matters provide a basis for a more thorough understanding of the Applicant's performance and conduct during the period of service under review. Examples of documentation that may be provided to the Board include proof of educational pursuits, verifiable employment records, documentation of community service, credible evidence of a substance free lifestyle and certification of non-involvement with civil authorities.

Issues Concerning Bad-Conduct Discharges (BCD) – Because relevant and material facts stated in a court-martial specification are presumed by the NDRB to be established facts, issues relating to the Applicant's innocence of charges for which he was found guilty cannot form a basis for relief. With respect to a discharge adjudged by a court-martial, the action of the NDRB is restricted to upgrades based on clemency. Clemency is an act of leniency that reduces the severity of the punishment imposed.

Board Membership: The names and votes of the members of the Board are recorded on the original of this document and may be obtained from the service records by writing to:

Secretary of the Navy Council of Review Boards
Attn: Naval Discharge Review Board
720 Kennon Street SE Rm 309
Washington Navy Yard DC 20374-5023

RECORD OF PROCEEDINGS
AIR FORCE BOARD FOR CORRECTION OF MILITARY RECORDS

IN THE MATTER OF: BC-2006-01924

DOCKET NUMBER:

INDEX CODE: 110.02

COUNSEL: NONE

HEARING DESIRED: NO

MANDATORY CASE COMPLETION DATE: 26 December 2007

APPLICANT REQUESTS THAT:

Her general (under honorable conditions) discharge be upgraded to an honorable discharge and remove the Article 15 dated 11 July 2000 from her records.

APPLICANT CONTENDS THAT:

Her discharge is inequitable because it does not reflect the quality of her service nor the honor in which she served; it was based on a controversial, isolated incident regarding her refusal to take the anthrax vaccine. Furthermore, the nonjudicial punishment she received should not be retained in her records because the administrative punishment itself is inequitable in light of current Air Force policy.

In support of her appeal the applicant submitted a personal statement, Enlisted Performance Report (EPR), separation documentation, Air Force Discharge Review Board (AFDRB) determination, Article 15, Current Air Force policy and Federal Cases and Supporting Affidavits.

Applicant's complete submission, with attachments, is at Exhibit A.

STATEMENT OF FACTS:

Applicant enlisted in the Regular Air Force (RegAF) on 22 April 1998 in the grade of airman basic (AB) for a period of four years.

The notification memorandum notifying the applicant that her commander was initiating discharge action is not on file in her master personnel records. However, according to the base legal office memorandum dated 18 July 2000, the applicant was properly notified on 12 July 2000. The applicant acknowledged receipt of the notification of discharge and after consulting with legal counsel submitted statements in her own behalf.

The specific reason for the discharge action was the applicant refused a direct order to take the Anthrax vaccination and received an Article 15. The applicant's commander in the recommendation for discharge recommended the applicant be discharged with a under honorable conditions (general) discharge without probation and rehabilitation.

The commander indicated in his recommendation for discharge that the applicant demonstrated a lack of commitment to the standards of order and discipline expected of an Air Force member. He further stated he utilized the rehabilitative tools available to afford the applicant the opportunity to become a productive member of the unit and responsible military member. In addition, he took steps to ensure the applicant received briefings from the Medical Group regarding the Anthrax vaccination.

On 18 July 2000, a legal review was conducted in which the staff judge advocate recommended the applicant receive an under honorable conditions (general) discharge.

On 18 July 2000, the discharge authority approved the separation and directed the applicant be discharged with a general (under honorable conditions) discharge without probation and rehabilitation.

Applicant was separated from the Air Force on 24 July 2000 under the provisions of AFI 36-3208, Administrative Separation of Airmen (misconduct), with an under honorable conditions (general) discharge. She served two years, three months and three days of active duty service.

The applicant submitted an appeal to the Air Force Board for Correction of Military Records (AFBCMR) on 11 September 2002 to have her Reenlistment Eligibility (RE) code changed to one that would allow her reentry into the AF. On 4 February 2003 the Board denied the applicant's request for a change in her RE code.

On 15 October 2003, the applicant appealed to the Air Force Discharge Review Board (AFDRB) to have her under honorable conditions (general) discharge upgraded to honorable. On 15 April 2004, the AFDRB concluded the applicant's misconduct was a significant departure from conduct

expected of all military members and the characterization of the discharge she received was appropriate.

_____

AIR FORCE EVALUATION:

AFLOA/JAJM recommends the requested relief be denied. They state an Article 15 should be set aside only when the evidence presented in the application demonstrates a material error or injustice. The applicant has failed to do so.

A commander who considers a case for disposition under Article 15 exercises personal discretion in evaluating the case, both as to whether nonjudicial punishment is appropriate and, if so, as to the nature and amount of punishment. Unless a commander's authority to act in a particular case is properly withheld, that commander's discretion is unfettered so long as the commander acts within the limits and parameters of the his legal authority. In the case of nonjudicial punishment, Congress (and the Secretary of the Air Force) has designated only two officials with the responsibility for determining the appropriateness of an otherwise lawful punishment: the commander and the appeal authority. As long as they are lawfully acting within the scope of the authority granted them by law, their judgment should not be disturbed to substitute a different after-the-fact view of others. Commanders "on the scene" have first-hand access to facts and appreciation for the needs of morale and discipline in their command that even the best-intentioned higher headquarters cannot match.

By electing to resolve the alleged violation of UCMJ Article 90 in the nonjudicial punishment forum, the applicant placed on her commander the responsibility to decide whether she committed the offense and whether nonjudicial punishment was appropriate. The applicant on the AF Form 3070 signed and initialed each step in the process indicating she was actively participating. The applicant had the opportunity to present evidence to the commander, and did in fact make a written presentation. The commander had the facts before him that the applicant elected to present. The commander considered all matter presented and concluded that applicant committed the alleged offense and that nonjudicial punishment was appropriate. The applicant after acknowledging her commander's decision waived her right to appeal.

The federal district court found that the Food and Drug Administration (FDA) failed to comply with public notice and comment procedures in classifying the anthrax vaccine as a Category I drug. On 27 October 2004, the court issued a permanent injunction preventing DOD from administering the anthrax vaccination to military members without their consent until the FDA properly classified it as a safe and effective drug for its intended use. The FDA issued such a classification on 19 December 2005, however, whereupon the

injunction dissolved.

Although, the DOD policy was adjusted for a period after the federal court decision to permit members to refuse the anthrax vaccination, DOD has now resumed mandatory anthrax vaccinations for specified military personnel.

A complete copy of the AFLOA/JAJM evaluation is at Exhibit C.

AFPC/DPPRS recommends denial. Based on the documentation on file in the master personnel records, the discharge was consistent with the procedural and substantive requirements of the discharge regulation. The discharge was within the discretion of the discharge authority. The applicant did not submit any evidence or identify any errors or injustices that occurred in the discharge processing. She has not provided any facts warranting a change in her character of service or removal of the Article 15.

A complete copy of the AF/DPPRS evaluation is at Exhibit D.

APPLICANT'S REVIEW OF AIR FORCE EVALUATION:

The applicant reviewed the Air Force evaluations and states the Air Force Personnel Center advisory does not address the merits of her case. The opinion only states the separation process was completed properly and there were no "errors or injustices that occurred in the discharge processing." However, the Air Force Legal Operations Agency advisory opinion squarely addressed the basis of her request.

At the time she was ordered to comply with the Anthrax Vaccination Immunization Program (AVIP), the anthrax vaccine absorbed (AVA) was not approved for its intended use, and the Department of Defense (DOD) was illegally mandating the AVIP. An injunction was issued by the U. S. District Court of the District of Columbia prohibiting the DOD from proceeding with the AVIP. The court stated the "AVA is an investigational drug and a drug being used for an unapproved purpose. As a result of this status, the DOD is in violation of 10 USC, Section 1107, Executive Order 13139, and DOD Directive 6200.2. It is irrelevant that this injunction expired once the Food and Drug Administration (FDA) approved the AVA for its intended use. What is important is that the AVA was not approved for use at the time she was punished and separated from the Air Force for refusing to take the AVA.

At the time she was ordered to comply with the AVIP, the

President had not issued a waiver allowing for an emergency use authorization. However, her commander was not implementing the AVIP pursuant to any emergency use authorization. It is irrelevant that the President subsequently issued a waiver allowing the DOD to administer the AVA for emergency uses subsequent to her discharge.

Since the submission of her request, DOD has resumed limited, mandatory AVA vaccinations. The mandate only applies to those persons in military units designated for homeland bioterrorism defense, those assigned to the U.S. Central Commander area of responsibility, and those assigned in Korea. All other persons retain the right to refuse the AVA and cannot be punished for refusing to take AVA. She was not assigned to any of these limited positions. Thus, if the current Air Force policy was in effect at the time she refused to take the AVA, she could not have been punished for such a refusal. Regardless, it was illegal to mandate participation in the AVIP at the time she refused to the AVA (Exhibit F).

THE BOARD CONCLUDES THAT:

1. The applicant has exhausted all remedies provided by existing law or regulations.

2. The application was not timely filed; however, it is in the interest of justice to excuse the failure to timely file.

3. Insufficient relevant evidence has been presented to demonstrate the existence of error or injustice regarding the applicant's request for removal from her records of the Article 15 imposed on 11 July 2000. We took notice of the applicant's complete submission in judging the merits of the case; however, we did not find it sufficient to override the rationale provided by AFLOA/JAJM. The evidence of record reflects that her commander determined that she had committed the alleged offense of willfully disobeying an order of a superior commissioned officer, and made the decision to impose nonjudicial punishment under Article 15. We note the applicant elected to accept nonjudicial punishment rather than being tried by court-martial. We are not inclined to disturb the discretionary judgment of commanding officers, who are closer to events, absent a strong showing of abuse of that authority. Therefore, in the absence of evidence which shows to our satisfaction that the applicant's substantial rights were violated, she was coerced to waive any of her rights, or the commander who imposed the nonjudicial punishment abused his discretionary authority, we conclude that no basis

exists to recommend favorable action on the applicant's request to remove the Article 15.

4. Sufficient relevant evidence has been presented to demonstrate the existence of an error or an injustice to warrant partial relief. The Board believes based on the documentation provided by the applicant, her military records and the mitigating factors of this case finds that the characterization of the applicant's service as less than honorable was harsh. The Board noted that prior to the events under review; the applicant was serving her country honorably and faithfully. Therefore, in view of the above, the Board recommends her records be corrected as indicated below.

THE BOARD RECOMMENDS THAT:

The pertinent military records of the Department of the Air Force relating to APPLICANT be corrected to show that on 24 July 2000, she was honorably discharged under the provisions of AFI 36-3208, Secretarial Authority, and issued a Separation Program Designator code of "KFF."

The following members of the Board considered AFBCMR Docket Number BC-2006-01924 in Executive Session on 10 April 2007 under the provisions of AFI 36-2603:
All members voted to correct the records as recommended. The following documentary evidence was considered:

Exhibit A. DD Form 149, dated 14 Jun 06, w/atchs.
Exhibit B. Master Personnel Records.
Exhibit C. Letter, AFLOA/JAJM, dated 19 Dec 06.
Exhibit D. Letter, AFPC/DPPRS, dated 10 Jan 07.
Exhibit E. Letter, SAF/MRBR, dated 16 Feb 07.
Exhibit F. Letter, Applicant, dated 14 Mar 07.

Panel Chair

MEMORANDUM FOR THE CHIEF OF STAFF

Having received and considered the recommendation of the Air Force Board for Correction of Military Records and under the authority of Section 1552, Title 10, United States Code (70A Stat 116) it is directed that:

The pertinent military records of the Department of the Air Force relating to , be corrected to show that on 24 July 2000, she was honorably discharged under the provisions of AFI 36-3208, Secretarial Authority, and issued a Separation Program Designator code of "KFF."

Director
Air Force Review Boards Agency

Little v. Barreme

Little v. Barreme, 6 U.S. (2 Cranch) 170 (1804), was a United States Supreme Court case in which the Court found that the President of the United States does not have "inherent authority" or "inherent powers" that allow him to ignore a law passed by the US Congress.

Contents

Summary

Facts

Procedural history

Issues

Holding

Reasoning

See also

References

Further reading

External links

Little v. Barreme	
Supreme Court of the United States	
Argued December 16, 19, 1801 Decided February 27, 1804	
Full case name	*George Little, et al. v. Barreme, et al.*
Citations	6 U.S. 170 (https://supreme.justia.com/us/6/170/case.html) (*more*) 2 Cranch 170; 2 L. Ed. 243; 1804 U.S. LEXIS 255
Court membership	
Chief Justice John Marshall	
Associate Justices William Cushing · William Paterson Samuel Chase · Bushrod Washington Alfred Moore	
Case opinions	
Majority	Marshall, joined by *unanimous*
Laws applied	
U.S. Const.	

Summary

A Presidential executive order was invalidated because the President was operating outside of his express Congressional authority.

Facts

The case derived from "an interesting and revealing incident" that occurred during the "Quasi War" with France at the end of the 18th century.[1] The frigate USS *Boston* commanded by captain George Little captured a Danish vessel, the *Flying Fish*, by order of the Secretary of the Navy on behalf of President John Adams "to intercept any suspected American ship sailing *to* or *from* a French port."[2] The Congress, however, had passed a law authorizing the navy to seize "vessels or cargoes [that] are apparently, as well as really, American" and "bound or sailing to any [French] port" in an attempt to prevent American vessels transporting goods to France. The *Flying Fish* was sailing from and not to a French port. Captain Little was declared to be liable for executing a command that was illegal. Little appealed to the Supreme Court, where the decision was upheld. Chief Justice John Marshall wrote "Is the officer who obeys [the

President's order] liable for damages sustained by this misconstruction of the act, or will his orders excuse him? ... the instructions cannot change the nature of the transaction, or legalize an act which without those instructions would have been a plain trespass."[3]

Procedural history

1. District Court, found for Petitioner
2. Circuit Court of Massachusetts, reversed, found for Respondent
3. United States Supreme Court, affirmed, found for Respondent

Issues

1. Whether an order of the President, which in effect attempts to make law, can override an act of Congress.
2. Officers are responsible for execution of illegal commands, despite nature of military chain of command.

Holding

No, an order of the President which is in contradiction with an act of Congress is illegal.

Reasoning

The legislative branch makes laws and the executive branch enforces the laws. The Act of Congress provided only for the capture of vessels traveling to France. "The Flying Fish was on a voyage from, not to, a French port, and was therefore, had she even been an American vessel, not liable to capture on the high seas." The Act limited the president's authority by only allowing the capture of certain vessels. The President acted contrary to these limitations.

See also

- List of United States Supreme Court cases, volume 6
- *United States v. Curtiss-Wright Export Corp.*

References

1. Woods, Thomas (2005-07-07) Presidential War Powers (http://archive.lewrockwell.com/woods/woods45.html), *LewRockwell.com*
2. Smith, Jean Edward (1996). *John Marshall: Definer of A Nation*. New York: Henry Holt and Company. p. 339. ISBN 0-8050-1389-X.
3. Blumrosen, Alfred; Blumrosen, Steven (2011). "Restoring the Congressional Duty to Declare War". *Rutgers Law Review*. **63**: 407–519.

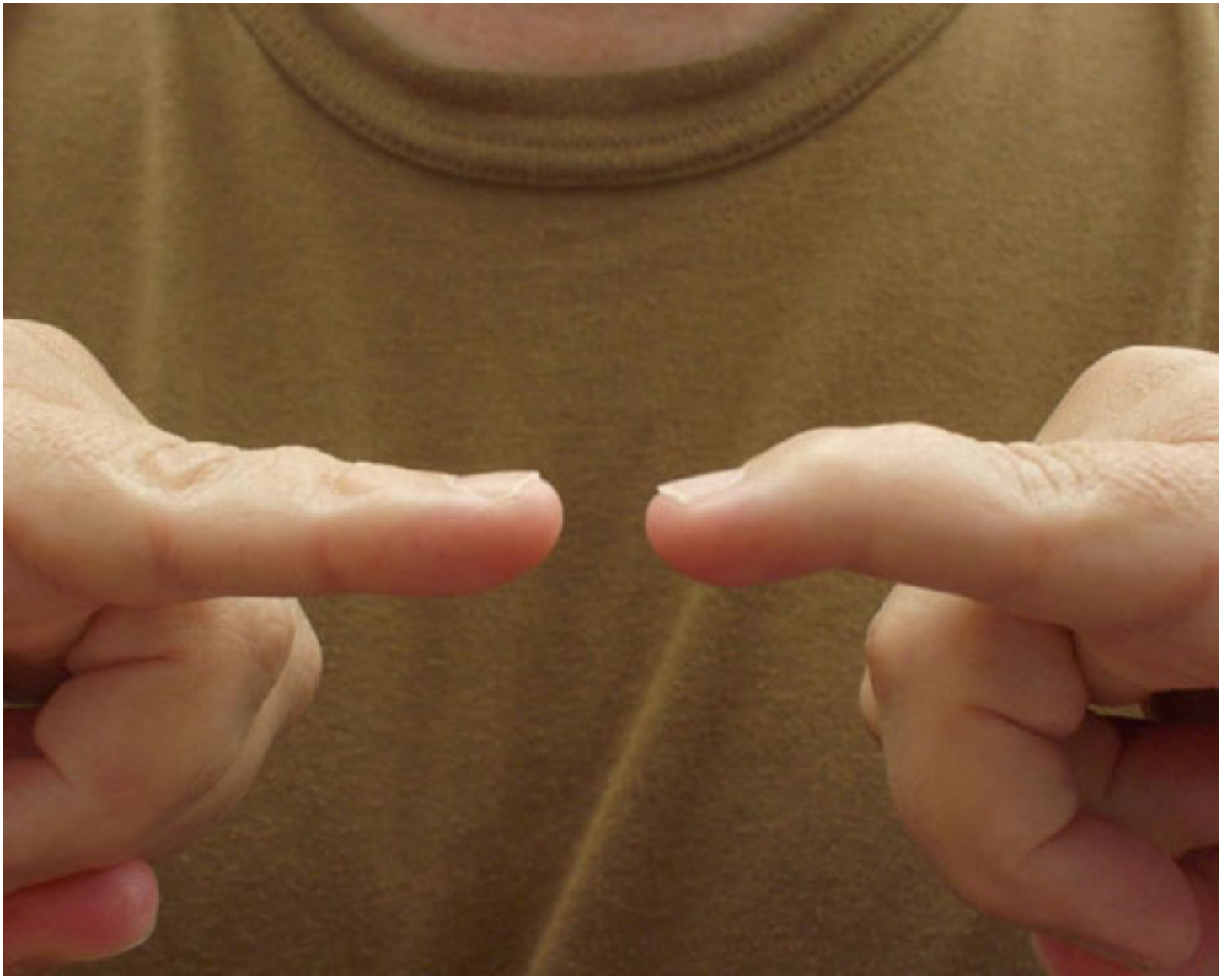
Further reading

- Glennon, Michael J. (1988). "Two Views of Presidential Foreign Affairs Power: *Little v. Barreme* or *Curtiss-Wright*?". *Yale Journal of International Law*. **13** (5): 5–20. SSRN 2620803 (https://ssrn.com/abstract=2620803).

External links

- Text of *Little v. Barreme*, 6 U.S. (2 Cranch) 170 (1804) is available from: Findlaw (http://caselaw.findlaw.com/us-supreme-court/6/170.html) Justia (https://supreme.justia.com/cases/federal/us/6/170/) OpenJurist (https://openjurist.org/6/us/170)
- LoveAllPeople.org: "Inherent Presidential Power Is Always Subject To The Inherent Congressional Powers To Make The Laws And Enforce Oversight Of The Executive Branch, Even In Time Of War" (http://www.loveallpeople.org/inherentpowers.html)

AF officer repeatedly refuses anthrax shot, but does not get day in court



(/polopoly_fs/1.10231.1273606373!/image/3125990720.jpg_gen/derivatives/landscape_900/3125

Lt. Col. Jay Lacklen shows the knots on his fingers. He suspects that the anthrax shots he has taken have caused the deformity.
SCOTT SCHONAUER / S&S

By SCOTT SCHONAUER | STARS AND STRIPES

Published: August 2, 2003

NAVAL STATION ROTA, Spain — Even with his 33-year military career on the line, Lt. Col. Jay Lacklen wants the Air Force to court-martial him.

By refusing to take another anthrax shot earlier this year, he thought he would get his wish. Facing a military judge, Lacklen said, would allow him to argue that the Pentagon's controversial vaccine contains a harmful booster called squalene, which he claims is causing a string of mysterious maladies in his squadron.

But instead of ordering him to court, his commander sent him on assignment to southern Spain.

While junior officers and enlisted servicemembers are getting thrown in jail for not taking the shot, Lacklen said his Dover, Del.-based squadron sent him on meaningless temporary duty to Naval Station Rota and Morón Air Base.

He believes the Air Force will not punish him because commanders are afraid they will lose in the courtroom.

“They’re scared,” said Lacklen, a reservist since 1981, “because I have the science” to win in court.

But in an e-mail to Stars and Stripes on Friday, Lacklen said his commander had given him until Friday to take the shot.

Large caches of biological and chemical weapons have yet to be found in Iraq and none was unleashed against U.S.-led troops during the war, but the military is continuing its goal to inoculate all of its 1.4 million servicemembers.

The Pentagon insists the vaccine is safe.

Right now, servicemembers take a series of six shots over the course of 18 months, along with an annual booster shot.

Almost half of the active-duty force has received the entire series of shots, but some have refused and paid dearly.

Since the military resumed inoculating servicemembers earlier this year, several have been booted out of the service or sent to jail.

In June, Navy aircraft mechanic Troy Goodwin, based at Lemoore, Calif., told the Los Angeles Times that he was sent to the brig after rejecting the shot.

In May, Army Reserve Pvt. Kamila Iwanowsk, 26, a petroleum specialist from Fort Drum, N.Y., refused the shot and received a bad-conduct discharge. She didn’t want to take it because, she said in a court-martial, it might harm any children she may bear.

On July 8, the military dismissed a Camp Lejeune, N.C.-based Marine helicopter pilot and sent him to jail for 25 days for not taking it. Lt. Erick Enz refused the vaccine on religious grounds.

More than 400 military personnel have been disciplined since the shot was made mandatory in 1998, according to the Pentagon. But Lacklen said he has avoided prosecution because his unit, the 326th Airlift Squadron, does not want the bad publicity.

On April 15, Lacklen refused in writing to take the shot. But instead of ordering him to take the vaccine, Lacklen said his commander, Lt. Col. Edward Poling, two days later grounded him and sent him to Spain.

ARTICLE CONTINUES BELOW

When he returned, he was immediately sent to Scott Air Force Base in Illinois to work as a scheduler.

Lacklen, a Vietnam War veteran with more than 12,000 flight hours, said he was not needed in Spain or Illinois and suggests he was sent on temporary duty to “avoid the situation.”

After Lacklen refused his shot, a more junior officer, Capt. Paul Staquet, also refused in writing, using the same wording Lacklen had used, but signed his own name to it. When he gave the letter to the squadron, he said he was threatened with a court-martial and a discharge. The thought of possibly getting kicked out of the military with a bad-conduct discharge was enough to cause Staquet to reluctantly take the shots.

“Nobody wants to walk around with a conviction on your record,” said Staquet, who has not suffered any side effects from the shots, but supports Lacklen.

In a complaint filed with the Defense Department’s inspector general on June 5, Lacklen accused his commander of a double standard.

Poling did not return phone and e-mail messages seeking an explanation or comment for this story, but Col. Bruce Davis, 512th Airlift Wing commander, said, “I’m sure you know that, as a commander, I can’t comment on any incident that may end up in a courts-martial.”

“All military members should expect equal protection, and equal sanction, from the military legal system,” Lacklen wrote in the complaint. “This is not the case in this instance.”

This is not the first time Dover has been embroiled in controversy over the vaccine.

In 1999, dozens of C-5 pilots from the base reported side effects after taking the shot. One senior officer resigned and 40 percent of the pilots in the Reserve wing left rather than take a shot.

Concerns by the pilots prompted Col. Felix M. Grieder, commander of the 436th Airlift Wing at Dover, to suspend the inoculation program, making it the first base to do so.

Since the base resumed the shots earlier this year, military personnel are reporting similar health problems they fear are caused by the shots.

Some of the aviators agreed to talk to Stars and Stripes on the condition their name is not used. They said they fear that if they talk, the Air Force will punish them for speaking out about the vaccine.

One pilot reported migraine headaches to the point of vomiting, temporary blindness and an itching rash that won't go away. Others have reported severe joint pain. One aviator in his 30s had arthritis so bad he had to take a prescription pain reliever.

Crewmembers have also had problems. A loadmaster reported having blackouts and chronic dizzy spells. Another person suffered from vertigo.

One of the pilots said he isn't sure if the vaccine caused his rash and other health problems but military doctors have done little to find out the cause. He said even if a military doctor thought there might be a link between the vaccine and the ailment, they would not admit it out of fear of retribution.

"We have seen with our own eyes those who are sick and watched them not get any help," he said. "It's shameful."

Another pilot had a bad reaction with the first shot, but was told to continue taking the rest of the shots.

"It does concern me," the pilot said. "I don't want to take another shot until they can prove this is just coincidental."

Lacklen has also had strange health problems after the first couple of shots. He has complained of joint pain and his fingers have developed odd-looking knots.

He doesn't blame the vaccine for the health problems but alleges that a substance called squalene is the culprit.

Squalene is manufactured in the liver of humans and some animals. It is a building block to make hormones and other substances in our body. It is also found in some foods.

In vaccines, it is used as a booster to work faster and longer. However, it was not approved by the federal Food and Drug Administration to be used in the anthrax vaccine.

When Tulane University in 1999 found the presence of the additive in 1991 Persian Gulf War veterans, squalene's safety became a hot topic. Some servicemembers speculated then that the anthrax vaccine might contain squalene as a booster and that is the reason for the side effects.

For years, the Pentagon denied there was any squalene in the shots. Then, the FDA tested all 50 lot numbers of the current vaccine in 1999 and found squalene traces in five of them. Dover Air Force Base received all five of these lot numbers.

The Pentagon says the amount of squalene found is so minute that it is "likely the result of squalene in the oil of a fingerprint not cleaned from the lab glassware." The Defense Department has an entire page of questions and answers about squalene on its anthrax Web site, www.anthrax.osd.mil, disputing the significance of squalene in the shot.

Lacklen and some of the pilots at Dover are not buying the explanation. They want the Defense Department to hire an independent lab to test vaccine lots for squalene.

While the Pentagon asserts that the adjuvant in the anthrax vaccine is aluminum hydroxide, Lacklen and the sick pilots said the reason they are skeptical is because other bases, which may not have gotten the same squalene lot Dover received, had not had similar health problems.

Those who talked to Stars and Stripes said they are willing to resume the shots as long as they know for sure the lots don't contain any trace of squalene.

"It's not the vaccine, it's what they added to it," Lacklen said.

Not all of the pilots agree with Lacklen. One pilot said that there are those in the squadron who think Lacklen is way off base. They did not receive any side effects from the shots.

But other pilots who talked to Stripes consider Lacklen, who is married and has four daughters, almost a hero for risking his career and speaking out.

Lacklen said the Air Force should do more to find out why some members of the wing are experiencing so many health problems and whether the vaccine is the reason.

“If we had wrecked an airplane, they would have had a team of people come down and figure out what went wrong,” Lacklen said. “A lot of people have gotten sick, but nobody has come.”

Lieutenant Colonel Thomas L. Rempfer
United States Air Force, Retired
[redacted]

April 10, 2018

Naval Discharge Review Board (NDRB)
720 Kennon Street SE, Suite 309
Washington DC 20374-5023

Dear NDRB:

I respectfully submit the following appeal on behalf of James D Muhammad, (former) Sergeant, USMC, for his case, and request your thoughtful consideration of his application.

The basis of my respectful request and recommendation to your panel rests on two fundamental points: precedent and clemency. I will begin by referencing a similarly situated USMC member whose precedent case met both the Board for Correction of Naval Records (BCNR) and the Naval Discharge Review Board (NDRB). I will then reflect on my own military experience to make the case that James Muhammad might be favorably considered for alteration of his record, despite the prior judgment of court-martial, for an upgrade of his discharge. I hope you will agree that clemency is warranted based both the passage of time and on inequities of discipline in the military compared to James Muhammad's dismissal.

5448-14/8917-13

First, the precedent case I hoped to call you attention to is TJR docket number [redacted] dated 17 June 2014. In this case, the block 24, character of service, was upgraded to general under honorable by the BCNR. I respectfully submit James Muhammad should receive similar treatment, hopefully fully honorable, based on his otherwise exemplary service record and his lengthy history of unblemished post-service conduct. Additionally, I respectfully request consideration that his block 28, narrative reason for separation, be altered to "Secretarial Authority," as in the precedent case, as opposed to court-martial, and that his block 26, separation code, be altered to reflect "LFF1." As in the precedent case, I believe based on the time elapsed, and good post-service conduct, that no useful purpose is served by the Petitioner's record continuing to reflect such a stigmatizing narrative reason for discharge.

Second, my request for clemency in James Muhammad's case appears justified since he was judged under a special court-martial, since this request is not appealing for an alteration of the judgment of the court-martial, since your board has the authority to upgrades discharges, and

because this is not a request to revoke the discharge. As well, clemency may be supported by looking at certain facts before and after the court-martial, as well as by examining my own military history under an inequity of justice standard. In my own case, I refused anthrax vaccine in 1998, was not punished through any judicial or non-judicial means, and served until 2015, wherein I reached mandatory retirement, with active duty benefits, and was discharged under fully honorable conditions. There are literally hundreds of servicemembers that were similarly treated, as opposed to the extreme disciplinary processes and penalties that James Muhammad underwent. The point of this appeal is not to re-adjudicate the core judgments in this case, but instead to ask for clemency based on a reflection of undeniable inequities of justice represented by James Muhammad's case when compared to others in our armed forces.

Finally, a brief summary of some of the facts from before and after James Muhammad's case may also be worthy of reflection as you consider his petition. Those facts include:

1. Federal Courts affirmed (341 F.Supp. 2d 20) the anthrax vaccine utilized in the Department of Defense Anthrax Vaccine Immunization Program (AVIP) force protection program was investigational, not licensed by the Food and Drug Administration (FDA), and inconsistent with Federal Regulations and U.S. law, prior to the December 19, 2005 publication by the FDA of a Final Rule for the Anthrax Vaccine Adsorbed (AVA) in the Federal Register (Volume 70, Number 242, page 75180-75198). In contrast, military courts upheld a presumption of legality of the AVIP, despite the fact that AVA was not licensed by the FDA until December 2005.

2. Multiple bipartisan Congressional hearings resulted in House Report 106-556 in April 2000. The report also found the Department of Defense's AVIP conflicted with FDA regulations, and declared the anthrax vaccine investigational absent a properly approved indication for use against inhaled anthrax. This report preceded and mirrored the later Article III Federal Court rulings detailed above in item 1.

3. Historical Department of Defense records, predating the AVIP, from 1985, by the U.S. Army, according to a Request for Proposal (RFP) for a new anthrax vaccine, acknowledged that there was "no vaccine in current use which will safely and effectively protect military personnel against exposure to this hazardous bacterial agent [Anthrax]." This RFP was the same year as the proposed, but never finalized, license rule was published in the Federal Register.

4. The FDA had issued a Notice of Intent to Revoke the Anthrax vaccine manufacturer's license in 1997, citing multiple instances of quality control deviations in 1998 & 1999. During this same timeframe the DoD and the manufacturer jointly submitted multiple Investigational New Drug (IND's) applications to the FDA in order to secure approval for an inhalation anthrax indication for AVA. Inhalation anthrax protection was the intended use of the vaccine, was not approved until the final license rule was published in 2005, and the IND's were cited by the Federal Court in 2003 to support the anthrax vaccine's investigational status in violation of 10 USC § 1034.

5. In April 2001, the White House directed the DoD to review the Anthrax Vaccine program. By August 2001, an internal Department of Defense review recommended the Secretary of Defense minimize use of the vaccine. The deliberative policy process was disrupted by the Anthrax Letter attacks in September and October 2001.

6. A preliminary report in August 2008, and a final report in February 2010, by the Federal Bureau of Investigation (FBI) and Department of Justice (DoJ) affirmed the perpetrator's motive in the anthrax letter attacks was "to save the failing anthrax vaccine program" by creating a "scenario where people all of a sudden realize the need to have this vaccine." The report revealed a United States Army anthrax vaccine scientist committed the crimes, and was successful in getting the failing program "rejuvenated … within a few months of the anthrax attacks." The report disclosed that following the attacks the "FDA fast-tracked the approval process and approved the Anthrax Vaccine Adsorbed … even though it didn't meet the original potency standards."

The facts above reveal, at a minimum, that there was considerable controversy surrounding the anthrax vaccine before and after the timeframe that James Muhammad was disciplined by the Department of the Navy. These facts provide perspective, and hopefully will engender compassion from the NDRB as to the reality that there were many events prejudicing good order and discipline related to the AVIP.

I appreciate your thoughtful consideration of this Petitioner's appeal based on precedent and under the standards for clemency. I am available to address any questions your board may have about my military service, or the points made in this letter, by contacting me at the following email and phone number: [redacted]

Very Respectfully,

[redacted]

LtCol Thomas L. Rempfer
United States Air Force, Retired

To: The Board of Correction of Naval Records

Re: Addendum for application
Docket No.: NR20180004948
James D. Muhammad, USMC
Submitted via: BCNR_Application@navy.mil

Contents

1- Letter of Explanation to The Board
2- Memorandum for Secretaries of the Military Departments; Guidance to Military Discharge Review Boards and Board for Correction of Military/ Naval Records Regarding Equity, Injustice, or Clemency Determinations (dated 25 Jul 2018) with attachment.
3- Anthrax Vaccine Adsorbed package insert

To: The Board of Correction of Naval Records

Re: Addendum for application
Docket No.: NR20180004948
James D. Muhammad
Submitted via: BCNR_Application@navy.mil

PREFACE
This application is hereby amended to include policy published after preparation and submission of Docket No. NR20180004948 to The Board. It is our belief that the referenced memorandum prepared and released by the Office of the Undersecretary of Defense is directly applicable, valid and supports Docket No. NR20180004948 highlighting similar individuals, causes and cases.

Reference: Memorandum for Secretaries of the Military Departments; Guidance to Military Discharge Review Boards and Board for Correction of Military/ Naval Records Regarding Equity, Injustice, or Clemency Determinations (dated 25 Jul 2018) with attachment.

Pertaining to the Memorandum Guidance relevant to Docket No. NR20180004948, We believe:

- The Petitioner's request is consistent with the intent of the Office of the Undersecretary of Defense in the redoubling of efforts to make Veterans aware of opportunities to apply for review of discharges and the increased attention paid to actions considered criminal convictions only in a military environment versus non-criminal matters in civil settings and the changing of State laws that repatriate individuals with civil rights, (right to vote, etc.)
- The Petitioner has demonstrated personal sacrifices and achievements consistent with overall policy and the punishment levied is excessive and offers little or no rehabilitative opportunity except by which the Petitioner has taken personal initiative to atone for what was

considered at that time to be an infraction. The Petitioner has overpaid to the degree of an imbalance of justice.

- Overall, the record accurately reflects that that Petitioner's characterization of service was not only HONORABLE but exemplary,marred by a sole event that culminated in a SCM BCD award which imbalances adjudication compared to other individuals with many or felonious infractions.
- The Memorandum Guidance at 6f specifies“Changes in policy, whereby a Service member under the same circumstances today would reasonably be expected to receive a more favorable outcome than the applicant received, may be grounds for relief”
    - The Petitioner wishes to bring attention to the fact that the UCMJ has been re-codified pursuant to the 2016 Military Justice Act effective 1 Jan 2019. We believe that this update would have affected the outcome of the petitioner’s matter in the following ways:
        - The Command pursued the case in a manner that could have been troublesome or possibly prohibited under Article 132 (Retaliation), as there were matters of willfully ineffective post-trial mishandling that resulted in being ordered to Appellate Leave during the time the new Commanding Officer and Convening Authority was to make a decision to accept the plea, findings and sentence. Petitioner believes that benefits of Doe v Rumsfeld would have been afforded to him had the command climate differed. Such possible Art 132 grievances were of a manner that evidence wasn’t preserved that could potentially substantiate today what is in the 2019 MCM as Article 134b (Obstruction of Justice) issues.
            - Post trial, Battalion Legal Officer, 1st Lt [redacted] made comments indicating that the command had determined a desired outcome of events. While signing the processing

paperwork for appellate leave, Major [redacted] (Bn Executive Officer) commented in Petitioner's presence that in hindsight indicates that he was aware of the Doe v Rumsfeld filing but the command remained determined to not disturb the charges. And, it is under current updated rules, the accused would have the ability to subpoena additional information, including emails that outlined and documented such a conspiratorial command climate[1].

- The new Convening Authority when coming aboard made an unsolicited statement to Petitioner prior to preparation and delivery of Record of Trial that "Your sentence isn't getting changed", lending further credibility that such comments possibly aided in bringing to issue at NAMALA, matters of Unlawful Command Influence and may meet the current standard for Art 134b Obstruction of Justice. At the time, the Petitioner resigned that the system had been impaired and despite best efforts was unable to obtain and/or retain evidence to present to this board.

- According to 2019 Manual for Court Martial R.C.M. 201(f)(1)(D) (ii) "A bad-conduct discharge... may not be adjudged by a special court-martial when the case is referred as a special court-martial consisting of a military judge alone under Article 16(c)(2)(A)." The applicant's special court-martial consisted of a military judge alone where a bad-conduct discharge was adjudged; this is no longer permitted under current procedures, which would mean that under the new rules the Petitioner would have been allowed to complete

[1]Petitioner was verbally told of an email composed by the Bn Legal Officer to Bn Commander and others which outlined such scenarios on how to "get him"; the informant was an unintended recipient but was unwilling to disclose the email

the contract term of enlistment, while accruing credit toward awards and promotions. Another possible result of this change could be similar to the above regarding the command having a "change of heart" once orders were received regarding Doe v Rumsfeld injunctive relief that they would apply such rules and orders retroactively and the Commanding Officer might feel better motivated to disapprove the finding and sentence.

- The Petitioner was not allowed trial delay until testimony of credible witnesses could be made available per MCM updates allowed in Rules 702 and 703. Chaplain [redacted] could have offered specific testimony that the matter of failure to perform lacked the required willfulness element or *mens rea* criminal intent necessary to be found guilty of Art 90, which would have changed the result to Not Guilty. In the case of the 2003 trial, the Command was able to enter into evidence that the Chaplain and Command Medical Officer were both unavailable to testify. A suitable replacement was not possible for the Chaplain, who had personal observations and a Senior Corpsman was substituted for the Medical Officer who could only testify about what he read in the record, not his personal observation.

- The Petitioner states that while the concept of **Patently Illegal orders** have not changed in the interim, the 2019 MCM Art 90 (c)(v) states "The order must not conflict with the statutory or constitutional rights of the person receiving the order." Although the Doe v Rumsfeld conclusion did not enlarge or amplify that any specific right was afforded to the Petitioner, there exists no doubt that the court enjoined the Department of Defense from administering the AVA vaccine to service members "absent informed

consent or Presidential waiver" . And, since prior to 2005, it lacked an approved license from the FDA, it could be reasonably inferred that the Petitioner's right to consent as Congress wrote in law was corollary with a right not give consent which was being violated, which is centrally at issue here.

- At issue post-trial, the Petitioner learned of Conditional Pleas pursuant to RCM 910(a)(2) and discovered the Detailed Defense Counsel (DC) did not inform him of the existence of such. Errantly believing that his only options were guilty or not-guilty. The Petitioner, against his conscience and persuaded by DC, changed his plea to guilty. If Petitioner possessed prior knowledge of the Doe v Rumsfeld filing, a change of plea would have been off the table, let alone executed. For the record, that Petitioner did not enter into any pretrial agreement to reduce severity of punishment in exchange for the change of plea. The guilty plea was done solely as a show of contrition once Petitioner realized the basis for his refusal was less than absolute. It was during trial pursuant to Rule 910(e) that the Military Judge (MJ) had a duty to weigh such guilty plea to determine that it met all legal requirements. It was later uncovered by Petitioner that had he properly understood the question asked by the MJ about a required element "willful" disobedience that Petitioner would have retracted plea and changed back to *not guilty*.

- As such, Petitioner believes that it would be neglectful not to direct attention to Rule 916(j) that specifically states that mistakes of law are pertinent when they are a relevant element such as in cases of WILLFULNESS of intent. It is an indisputable fact that

Petitioner believed he was taking a right and lawful act by refusing to obey the order to receive the Anthrax Vaccination.

- According to R.C.M. 201(f)(2)(B)(ii) new procedures and limitations are now imposed upon Special Court Martials (SCM) to adjudge a Bad Conduct Discharge. This would have applied to Petitioner due to the case referred to as a SCM with a MJ alone.

- According to RCM 1210, Petitioner could have requested a new trial on the basis of "bad faith" of the Government as opined by the DC Circuit Court on 20070821 that "the Government's position was not substantially justified" when the Doe plaintiffs requested payment of attorney fees[2]. RCM 1210 now allows this special rule that Petitioner would have been able to request a new trial until 2010, if the Petitioner was aware of such a rule or had the rule existed at the time. The memo specifically asks for this type of information that could change the outcome based upon new rules or regulations.

- Evidence as submitted in Petitioner's request is directly from the Federal Circuit Court acting in official capacity and is used to support contention that the outcome would have changed, given the benefit of hindsight.
- BCNR consider the uniformity and unfair disparities in Petitioner's punishment as a basis of relief as demonstrated in applicant's package submission (6j)
- Petitioner is requesting relief for a non-violent matter (6k)
- Applicant has clearly demonstrated a redemptive value to society as amplified in paragraph 6a-f, 6i
- Petitioner has been candid with the BCNR (7a), in fact what is not reflected in the record is that the Petitioner [redacted]

[2] See June 2018 submission under this docket at page listed as BCNR-121

[redacted]

this time. Petitioner was aware when refusing vaccination that the AVA package insert contained cautions [redacted] Petitioner didn't mention this at time of refusal because he didn't determine it as justification to refuse.

- Petitioner's conduct has been exemplary post service with evidence and has and continues to improve his standing in society (7d, 7k, 7n)
- It has been 16 years since the SCM (7f)
- Character and reputation of Petitioner has been established by numerous letters of recommendation and signed statements (7i, 7p, 7q)

In Conclusion:

We believe

The Petitioner's submitted testimony establishes facts and merits supportive of relief that are well founded, articulated and supported by multiple sources.

The Petitioner's submission at Docket No NR20180004948 demonstrates the timing of the court martial conviction would have produced a different result just a short while later in December 2005 with the conclusion of Doe v Rumsfeld which clarified the legal status of the AVIP program and the rights that Congress had already granted in law.

We believe that Docket No NR20180004948 merits appropriate relief.

[redacted]

James D. Muhammad 10 March 2019

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

PERSONNEL AND READINESS

JUL 25 2018

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS

SUBJECT: Guidance to Military Discharge Review Boards and Boards for Correction of Military / Naval Records Regarding Equity, Injustice, or Clemency Determinations

The Department has evaluated numerous aspects of the Service Discharge Review Boards (DRBs) and Boards for Correction of Military / Naval Records (BCM/NRs) over the last two years. We have redoubled our efforts to ensure veterans are aware of their opportunities to request review of their discharges and other military records. We have initiated several outreach efforts to spread the word and invite feedback from veterans and organizations that assist veterans and active duty members, and issued substantive clarifying guidance on Board consideration of mental health conditions and sexual assault or sexual harassment experiences. And, we have partnered with the Department of Veterans Affairs to develop a web-based tool that provides customized guidance for veterans who want to upgrade their discharges. But our work is not yet done.

Increasing attention is being paid to pardons for criminal convictions and the circumstances under which citizens should be considered for second chances and the restoration of rights forfeited as a result of such convictions. Many states have developed processes for restoring basic civil rights to felons, such as the right to vote, hold office, or sit on a jury, and many states have developed veterans' courts to consider special circumstances associated with military service. States do not have authority, however, to correct military records or discharges.

The Military Departments, operating through DRBs and BCM/NRs, have the authority to upgrade discharges or correct military records to ensure fundamental fairness. DRBs and BCM/NRs have tremendous responsibility and perform their tasks with remarkable professionalism, but further guidance to inform Board decisions on applications based on pardons for criminal convictions is required.

The attached guidance closes this gap and sets clear standards. While not everyone should be pardoned, forgiven, or upgraded, in some cases, fairness dictates that relief should be granted. We trust our Boards to apply this guidance and give appropriate consideration to every application for relief.

Military Department Secretaries will ensure that Board members are familiar with and appropriately trained on this guidance within 90 days. My point of contact is Monica Trucco, Director, Office of Legal Policy, who may be reached at (703) 697-3387 or monica.a.trucco.civ@mail.mil.

Robert L. Wilkie

Attachment:
As stated

cc:
Chairman of the Joint Chiefs of Staff
General Counsel of the Department of Defense
Assistant Secretary of Defense for Legislative Affairs
Assistant Secretary to the Defense for Public Affairs

Attachment

Guidance to Military Discharge Review Boards and Boards for Correction of Military / Naval Records Regarding Equity, Injustice, or Clemency Determinations

Generally

1. This document provides standards for Discharge Review Boards (DRBs) and Boards for Correction of Military / Naval Records (BCM/NRs) in determining whether relief is warranted on the basis of equity, injustice, or clemency.

2. DRBs are authorized to grant relief on the basis of issues of equity or propriety. BCM/NRs are authorized to grant relief for errors or injustices. These standards, specifically equity for DRBs and relief for injustice for BCM/NRs, authorize both boards to grant relief in order to ensure fundamental fairness.

3. Clemency refers to relief specifically granted from a criminal sentence and is a part of the broad authority that DRBs and BCM/NRs have to ensure fundamental fairness. BCM/NRs may grant clemency regardless of the court-martial forum; however, DRBs are limited in their exercise of clemency in that they may not exercise clemency for discharges or dismissals issued at a general court-martial.

4. This guidance applies to more than clemency from sentencing in a court-martial; it also applies to any other corrections, including changes in a discharge, which may be warranted on equity or relief from injustice grounds.

5. This guidance does not mandate relief, but rather provides standards and principles to guide DRBs and BCM/NRs in application of their equitable relief authority. Each case will be assessed on its own merits. The relative weight of each principle and whether the principle supports relief in a particular case, are within the sound discretion of each board.

6. In determining whether to grant relief on the basis of equity, an injustice, or clemency grounds, DRBs and BCM/NRs shall consider the following:

a. It is consistent with military custom and practice to honor sacrifices and achievements, to punish only to the extent necessary, to rehabilitate to the greatest extent possible, and to favor second chances in situations in which individuals have paid for their misdeeds.

b. Relief should not be reserved only for those with exceptional aptitude; rather character and rehabilitation should weigh more heavily than achievement alone. An applicant need not, for example, attain high academic or professional achievement in order to demonstrate sufficient rehabilitation to support relief.

c. An honorable discharge characterization does not require flawless military service. Many veterans are separated with an honorable characterization despite some relatively minor or infrequent misconduct.

d. Evidence in support of relief may come from sources other than a veteran's service record.

e. A veteran or Service member's sworn testimony alone, oral or written, may establish the existence of a fact supportive of relief.

f. Changes in policy, whereby a Service member under the same circumstances today would reasonably be expected to receive a more favorable outcome than the applicant received, may be grounds for relief.

g. The relative severity of some misconduct can change over time, thereby changing the relative weight of the misconduct in the case of the mitigating evidence in a case. For example, marijuana use is still unlawful in the military, but it is now legal under state law in some states and it may be viewed, in the context of mitigating evidence, as less severe today than it was decades ago.

h. Requests for relief based in whole or in part on a mental health condition, including post-traumatic stress disorder (PTSD); Traumatic Brain Injury (TBI); or a sexual assault or sexual harassment experience, should be considered for relief on equitable, injustice, or clemency grounds whenever there is insufficient evidence to warrant relief for an error or impropriety.

i. Evidence submitted by a government official with oversight or responsibility for the matter at issue and that acknowledges a relevant error or injustice was committed, provided that it is submitted in his or her official capacity, should be favorably considered as establishing a grounds for relief.

j. Similarly situated Service members sometimes receive disparate punishments. A Service member in one location could face court-martial for an offense that routinely is handled administratively across the Service. This can happen for a variety of lawful reasons, for example, when a unit or command finds it necessary to step up disciplinary efforts to address a string of alcohol- or drug-related incidents, or because attitudes about a particular offense vary between different career fields, units, installations, or organizations. While a court-martial or a command would be within its authority to choose a specific disposition forum or issue a certain punishment, DRBs and BCM/NRs should nevertheless consider uniformity and unfair disparities in punishments as a basis for relief.

k. Relief is generally more appropriate for nonviolent offenses than for violent offenses.

l. Changes to the narrative reason for a discharge and/or an upgraded character of discharge granted solely on equity, injustice, or clemency grounds normally should not result in

separation pay, retroactive promotions, the payment of past medical expenses, or similar benefits that might have been received if the original discharge had been for the revised reason or had the upgraded character.

7. In determining whether to grant relief on the basis of equity, an injustice, or clemency grounds, DRBs and BCM/NRs should also consider the following, as applicable:

a. An applicant's candor

b. Whether the punishment, including any collateral consequences, was too harsh

c. The aggravating and mitigating facts related to the record or punishment from which the veteran or Service member wants relief

d. Positive or negative post-conviction conduct, including any arrests, criminal charges, or any convictions since the incident at issue

e. Severity of misconduct

f. Length of time since misconduct

g. Acceptance of responsibility, remorse, or atonement for misconduct

h. The degree to which the requested relief is necessary for the applicant

i. Character and reputation of applicant

j. Critical illness or old age

k. Meritorious service in government or other endeavors

l. Evidence of rehabilitation

m. Availability of other remedies

n. Job history

o. Whether misconduct may have been youthful indiscretion

p. Character references

q. Letters of recommendation

r. Victim support for, or opposition to relief, and any reasons provided

50483 Rev. 3/99

ANTHRAX VACCINE ADSORBED

DESCRIPTION

Anthrax Vaccine Adsorbed is a sterile product made from filtrates of microaerophilic cultures of an avirulent, nonencapsulated strain of ***Bacillus anthracis*** which elaborates the protective antigen during the growth period. The cultures are grown in a synthetic liquid medium and the final product is prepared from sterile filtered culture fluid. The potency of this product is confirmed according to the U.S. Food and Drug regulations (21 CFR 620.23): Additional Standards for Anthrax Vaccine Adsorbed. The final product contains no more than 2.4 mg aluminum hydroxide (equivalent to 0.83 mg aluminum) per 0.5 mL dose. Formaldehyde, in a final concentration not to exceed 0.02%, and benzethonium chloride, 0.0025%, are added as preservatives.

CLINICAL PHARMACOLOGY

Anthrax Vaccine Adsorbed is used in man to promote increased resistance to ***Bacillus anthracis*** by active immunization (1,2).

INDICATIONS AND USAGE

Immunization with Anthrax Vaccine Adsorbed is recommended for individuals who may come in contact with animal products such as hides, hair, or bones which come from anthrax endemic areas and may be contaminated with ***Bacillus anthracis*** **spores;** and for individuals engaged in diagnostic or investigational activities which may bring them into contact with ***B. anthracis*** **spores** (1,5). It is also recommended for high risk persons such as veterinarians and others handling potentially infected animals. Since the risk of exposure to anthrax infection in the general population is slight, routine immunization is not recommended.
If a person has not previously been immunized against anthrax, injection of this product following exposure to anthrax bacilli will not protect against infection.

CONTRAINDICATIONS

A history of a severe reaction to a previous dose of anthrax vaccine is a contraindication to immunization with this vaccine.

WARNINGS

1. Any acute respiratory disease or other active infection is generally considered to be adequate reason for deferring an injection.
2. Persons receiving cortico-steroid therapy or other agents which would tend to depress the immune response may not be adequately immunized with the dosage schedule recommended. If the therapy is short termed, immunization should be delayed. If the therapy is long termed, an extra dose of vaccine should be given a month or more after therapy is discontinued.

PRECAUTIONS

1. ***General:*** Epinephrine solution, 1:1000, should always be available for immediate use in case an anaphylactic reaction should occur, even though such reactions are rare.
2. ***Carcinogenesis, Mutagenesis, Impairment of Fertility:*** Studies have not been performed to ascertain whether Anthrax Vaccine Adsorbed has carcinogenic action, or any effect on fertility.
3. ***Pregnancy:*** PREGNANCY CATEGORY C. ANTHRAX VACCINE ADSORBED Animal reproduction studies have not been conducted with Anthrax Vaccine Adsorbed. It is also not known whether Anthrax Vaccine Adsorbed can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Anthrax Vaccine Adsorbed should be given to pregnant women only if clearly needed.
4. ***Pediatric Use:*** This antigen should be administered only to healthy men and women from 18 to 65 years of age because investigations to date have been conducted exclusively in that population.

ADVERSE REACTIONS

Local Reactions: Mild local reactions occur in approximately thirty per cent of recipients and consist of a small ring of erythema, 1-2 cm in diameter, plus slight local tenderness(1). This reaction usually occurs within 24 hours and begins to subside by 48 hours. Occasionally, the erythema increases to 3 to 5 cm in diameter. Local reactions tend to increase in severity by the 5th injection and then may decrease in severity with subsequent doses.
Moderate local reactions which occur in 4 per cent of recipients of a second injection are defined by an inflammatory reaction greater than 5 cm diameter.

These may be pruritic. Subcutaneous nodules may occur at the injection site and persist for several weeks in a few persons. A moderate local reaction can occur if the vaccine is given to anyone with a past history of anthrax infection.
More severe local reactions are less frequent and consist of extensive edema of the forearm in addition to the local inflammatory reaction.
All local reactions have been reversible.
Systemic Reactions: Systemic reactions which occur in fewer than 0.2 per cent of recipients have been characterized by malaise and lassitude. Chills and fever have been reported in only a few cases. In such instances, immunization should be discontinued.

All adverse reactions thought by a physician possibly to have been related to this product should be directed to the BioPort Corporation (517) 327-1500 during regular working hours and (517) 327-7200 during off hours.

DOSAGE AND ADMINISTRATION

Dosage

Primary immunization consists of three subcutaneous injections, 0.5 mL each, given 2 weeks apart followed by three additional subcutaneous injections, 0.5 mL each, given at 6, 12 and 18 months(1).
If immunity is to be maintained, subsequent booster injections of 0.5 mL of anthrax vaccine at one year intervals are recommended.

Administration

1. Use a separate sterile needle and syringe for each patient to avoid transmission of viral hepatitis and other infectious agents.
2. Shake the bottle thoroughly to ensure that the suspension is homogeneous during withdrawal. The rubber stopper should be treated with an appropriate disinfectant and allowed to dry before inserting the needle.
3. This preparation must be give subcutaneously after cleansing the overlying skin with an antiseptic.
4. Follow the usual precautions to avoid intravenous injection.
5. After withdrawing the needle, the injection site may be massaged briefly and gently to promote dispersal of the vaccine.
6. The same site should not be used for more than one injection of this vaccine.
7. Do not syringe-mix with any other product.
8. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Anthrax Vaccine Adsorbed is supplied in 5 mL vials containing 10 doses each.

STORAGE

THIS PRODUCT SHOULD BE STORED AT AT 2 TO 8 degrees C (35.6 to 46.4 degrees F). Do not freeze. Do not use after the expiration date given on the package.

REFERENCES

1. Brachman, P. S., et. al. Field Evaluation of a Human Anthrax Vaccine. Amer. J. Pub. Health, 52:632-645 (1962).
2. Editorial: Vaccine Against Antrax. Brit. Med, J., 2:717-718(1965).
3. Advisory Committee for Immunization Practices. Adult Immunization, Morbidity and Mortality Report, 33(15):33-34, 1984.
4. Committee on Immunization, ***Guide for Adult Immunization, 1985,*** Amer. Col. Physicians, Philadelphia, PA (1985).
5. Report of Committee on Infectious Diseases, 19th Edition, Amer. Acad. Pediatrics, Evanston, IL (1982).

These recommendations are prepared by the BioPort Corporation only for the guidance of the physician. They do not replace the experience and judgement of the physician, who should be familiar with the recent pertinent medical literature before administering any biologic product

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