

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

JOHN DOE #1 et al.	*	
	*	
Plaintiffs,	*	
	*	Civil Action No.: 1:03CV00707 (EGS)
v.	*	
	*	
DONALD H. RUMSFELD <u>et al.</u> ,	*	
	*	
Defendants.	*	
* * * * *	* * * * *	

**AMICUS CURIAE BRIEF OF
THE NATIONAL VACCINE INFORMATION CENTER,
THE NATIONAL GULF WAR RESOURCE CENTER AND
THE MILITARY VACCINE EDUCATION CENTER
OPPOSING EMERGENCY MOTION TO MODIFY INJUNCTION**

By and through undersigned counsel, The National Vaccine Information Center (“NVIC”), the National Gulf War Resource Center (“NGWRC”), and Military Vaccine Education Center, Inc. (“MVEC”) move this Court in the above-captioned case to deny Defendants “Emergency Motion to Modify Injunction” so as to allow the Department of Defense (“DoD”) to resume its use of Anthrax Vaccine Absorbed (“AVA”) without informed consent, and in support thereof Petitioners submit the following brief:

Nature of the Case

On October 27, 2004 this Court issued a permanent injunction in this action, ordering that “[u]nless 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.*”
[emphasis added]

On December 10, 2004 the Deputy Secretary of Defense, Paul Wolfowitz, requested in a memo to the Secretary of Health and Human Services (“HHS”) Tommy Thompson that he declare an emergency under the provisions of the 2004 Project BioShield Act (“BioShield Act”) in response to a purported anthrax threat to our country’s armed forces “serving in Central Command and Korea.” *See* Defendants’ Emergency Motion, Ex. 4.

On Jan 14, 2005 the Secretary of “HHS” complied with the DoD request, “declar[ing] an emergency justifying the authorization of the emergency use of Anthrax Vaccine Adsorbed subject to the conditions described in the authorization issued under 21 U.S.C. 360bbb(a).” *See* 70 Fed. Reg. 5450-5451 (Feb 2, 2005), and Defendants’ Emergency Motion, Ex. 3.¹

On January 28, 2005, the Commissioner of the Food and Drug Administration (“FDA”) promulgated an Emergency Use Authorization to implement the HHS Secretary’s declaration of emergency. *See* 70 Fed. Reg. 5452-5456 (Feb 2, 2005), and Defendants’ Emergency Motion, Ex. 2.

On February 4, 2005, Defendants petitioned this Court with their “Emergency Motion to Amend” the aforementioned permanent injunction to allow so-called “voluntary” anthrax vaccinations without true informed consent pursuant to the FDA’s emergency use authorization (“EUA”).

For the reasons set forth below, Petitioners respectfully request that this Court deny the Defendants’ request for the “emergency” relief sought.

¹ The HHS emergency declaration was facially flawed in that it was not geographically restricted to those areas specified by the Deputy Secretary of Defense’s request.

Legal Argument

At the heart of the Defendants' emergency motion is the interaction between two statutes, each enacted to serve opposing purposes: 10 U.S.C. 1107 (enacted to protect service members who the military "requests or requires" to take questionable medications by requiring that they be fully informed "regarding the possible side effects" of the drug); and 21 U.S.C. 360bbb-3 (enacted to facilitate the use of otherwise unapproved drugs in case of emergencies).

Petitioners seek to argue and demonstrate that (a) the emergency use authorization was granted improperly as an abuse of discretion by the Secretary of HHS in an effort to circumvent this Honorable Court's prior orders; and (b) the emergency use authorization granted is violative of 10 U.S.C. 1107, even when read in concert with 21 U.S.C. 360bbb-3.

Abuse of Discretion

21 U.S.C. 360bbb-3(c) sets forth specific criteria for when an emergency use authorization may be issued:

only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved), the Secretary concludes--

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that--

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and
(4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

The issuance of the emergency use authorization was clearly an abuse of discretion, because (a) the HHS Secretary did not consider “the totality of scientific evidence” relating to “the known and potential risks of the product” before issuance of the authorization; and (b) because there are adequate, approved, and available alternatives to the AVA.

- - - Known and Potential Risks of the Product

Despite stating on the surface that the authorization was based upon a review of “the totality of the scientific evidence,” it is clear from the authorization itself that the only real safety data willingly reviewed were two out-dated studies.² The use of these two unrepresentative dated “studies” (discussed at length below) to assert AVA’s safety willfully ignores the DoD’s entire experience in administering the vaccine to over 1.3 million service members either during the 1991 Gulf War or during the 1998-2004 Anthrax Vaccine Immunization Program (“AVIP”). This experience resulted in a substantial revision to the FDA-approved package insert in January 2002 to include a wide range of chronic autoimmune disorders, heightened pregnancy risk and six deaths.³

The first safety study referenced, the 1967-1971 Centers for Disease Control open-label safety study, was not an “adequate and controlled clinical trial” of the present vaccine, as it measured only short-term adverse reactions, and used anthrax vaccine manufactured prior to

² See Ex. B, Declaration of Meryl Nass, M.D., as well as the legal discussion on the issue addressed at length below. Please note that all “Declarations” submitted in support of this petition and amicus brief are unsigned, but true and exact copies of faxed signed copies are available from counsel for Petitioners.

³ Biothrax (anthrax vaccine absorbed), FDA-approved package insert, Jan 2002.

<http://www.fda.gov/OHRMS/DOCKETS/98fr/05n-0040-bkg0001.pdf>

significant changes to the manufacturing process in the early 1990's, that the Army has acknowledged increased potency by up to 100 times.⁴

The second safety study referenced was a 1996-1999 Army study of 28 so-called volunteers "conducted as part of a randomized clinical study conducted by the U.S. Army Medical Research Institute of Infectious Diseases." This study was certainly not an "adequate and controlled clinical trial,"⁵ as it measured only short-term adverse reactions, and used an absurdly small sample size. It is also unclear if this study was ever published or peer-reviewed.⁶

The highly selective use of two unrepresentative "studies" to support the alleged review of the AVA's safety in the EUA and the impropriety of those studies is only a small portion of the abuse of discretion, which is far greater demonstrated by the willful ignorance of the adverse reactions to the present vaccine. Almost 99% of the use of this vaccine has occurred after 1990,

⁴ GAO-02-181T, Anthrax Vaccine: Changes to the Manufacturing Process, Oct 23, 2001, p. 5: "the Department of Defense found up to a hundredfold increase in the protective antigen levels in lots produced after the filter change that year [1990]." See <http://www.gao.gov/cgi-bin/getrpt?gao-02-181t>.

⁵ The 1979 FDA Expert Review Panel report explicitly described the standards for well-controlled trials in its "Generic Statement on Requirements for a Well-Controlled Field Trial." The currently licensed anthrax vaccine (AVA) has never met this standard, nor did the Brachman field trial of a different vaccine.

Additionally, it is unclear if the "volunteers" in this experiment were Army employees who were required to take the vaccine as a condition of employment. If so, this violates FDA's agency guidance on clinical trials. Last, since Ft. Detrick had a history of manufacturing anthrax vaccine itself, it is also unclear whether the anthrax vaccine used in the 1996-1999 Army study cited by the FDA was actually the AVA under review or one manufactured by Fort Detrick.

Furthermore, "no longer acceptable are comparisons of the frequencies of disease in those who do and do not volunteer for a vaccine study. The fallacy of this approach is that volunteers differ from non-volunteers in many important aspects...." See 50 Fed. Reg. 51012-51013 (Dec. 13, 1985) (evaluating the vaccine). The 1996-1999 Army "study" cited by FDA may also fail for this reason in that the 28 "volunteers" were not really volunteers; but until the FDA discloses the details of what is apparently an unpublished study, there should be a presumption against the relevance (or veracity) of this purported study of AVA safety.

⁶ The 28 "volunteers" may have been part of an Army study of 173 anthrax vaccine recipients that was published in 2002. However, the FDA has not made this association in the Emergency Use Authorization. (See Ex. "B" (Nass Declaration) at 7 and n. 3).

primarily by military personnel. Despite well-documented resistance by the military medical community to reporting adverse reactions, service members have submitted thousands of reports to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS). Over just the past two years (2003-2004), there have been at least 1,874 AVA adverse reaction reports submitted to VAERS, and more than 1600 prior reports had been submitted since AVIP began in 1998.⁷ There is no discussion or review of this recent substantive safety data, nor is there an explanation for its absence.

FDA's highly selective use of two unrepresentative "studies" to assert AVA's safety also willfully ignores over 1,000 patient medical records of service members treated for serious adverse reactions, principally to anthrax vaccine, at the Walter Reed National Vaccine Healthcare Center⁸ and three subsidiary Vaccine Healthcare Centers since it was established in 2001.

The intentional failure to review and discuss this known important safety data in reaching the authorization is not an act in isolation. Unfortunately, it comes on the heels of numerous other moral, ethical, and possibly legal violations by the individuals at the DoD, HHS and the FDA who are otherwise appointed to protect the service members and citizenry of our country. These include the following:

⁷ The 1998-2004 AVIP experience is documented by servicemember reports to the FDA/CDC Vaccine Adverse Reporting System, including 1,068 reports in 2003; 806 reports in 2004, and 1,623 reports prior to December 2001. Spreadsheets setting forth the substance of these reports for 2003 and 2004 are attached hereto as Exhibits "C" and "D." The 2003-2004 reports are highly significant in that they mostly represent adverse reactions to "post-renovation" AVA manufactured and approved after FDA allowed BioPort to resume production in January 2002 (following a four-year shutdown).

⁸ See www.vhcinfo.org

- a. DoD has failed to publicly report the results of a pregnancy study of birth defects arising from the vaccine conducted by Navy Commander Dr. Margaret Ryan, M.D.⁹ The preliminary results of this study were released in late 2001 and reflected in the CDC informed consent document given to postal workers and Congressional staff who were offered post-exposure anthrax vaccine in December 2001.¹⁰ The results of this as-yet unpublished study were also the reason the AVA pregnancy risk category was raised in the January 2002 revision of the FDA-approved package insert.¹¹ Nonetheless, the DoD refuses to publish this report, and it was not reviewed in furtherance of the authorization.
- b. DoD has failed to report and FDA has failed to investigate an epidemic of adverse reactions to anthrax vaccine associated with the use at Dover Air Force Base in 1998-2000, despite being informed by more than one officer in detailed reports and analyses, and despite demands from Delaware's congressional representatives.¹²
- c. DoD has failed to disclose, and the FDA has failed to consider in its authorization, a 1999 RAND Corporation report on the role of vaccines, including anthrax vaccine, in the onset of Gulf War Illness.¹³ Contracted for by the DoD, this report is the only report out of eight in this RAND series that has never been released or published by the DoD.¹⁴

⁹ M. Ryan, et.al., "The Department of Defense Birth Defects Registry: Overview of a New Surveillance System", Department of Defense Center for Deployment Health Research, Naval Health Research Center, San Diego, CA.

www.nbdpn.org/archives/2001/report2001/6dod.pdf.

¹⁰ Laura Johannes, "Anthrax Vaccine May Increase Incidence Of Birth Defects For Pregnant Women", Wall Street Journal, Jan 16, 2002

¹¹ FDA-approved package insert states AVA is now a Category D pregnancy risk: "Preliminary results of a recent unpublished retrospective study of infants born to women in the U.S. military service worldwide in 1998 and 1999 suggest that the vaccine may be linked with an increase in the number of birth defects when given during pregnancy (unpublished data, Department of Defense)." Prior to Jan 2002, AVA was a Category C pregnancy risk: "Adequate, well-controlled human studies are lacking, and animal studies have shown a risk to the fetus or are lacking as well. There is a chance of fetal harm if the drug is administered during pregnancy; but the potential benefits may outweigh the potential risk."

¹² See Capt Michele Piel, Dover AFB – testimony to House Subcommittee on National Security, Veterans' Affairs and International Relations, Jul 21, 1999; Lt Richard Rovet, Dover AFB – testimony to House Subcommittee on National Security, Veterans' Affairs and International Relations, Jul 21, 1999; Sen. Biden, Sen. Carper, Rep. Castle letter to Secretary of Defense Rumsfeld, Oct 13, 2004, quoted in Lee Williams and Hiran Ratnayake, "Biden, Carper, Castle want answers", Delaware News Journal, Oct 12, 2004.

<http://www.delawareonline.com/newsjournal/local/2004/10/12biden,carper,ca.html>;

http://www.delawareonline.com/newsjournal/local/2004/10/15squalene_letter.html).

¹³ Beatrice Alexandra Golomb, "Volume 3: Immunizations", "A Review of the Scientific Literature as It Pertains to Gulf War Illnesses (Series)", RAND

<http://www.rand.org/multi/gulfwar/publications.html>

In 1999, Dr. Beatrice A. Golomb, MD, PhD, a RAND contract researcher, completed a report on immunizations given during the Gulf War. That report, as is evident from the RAND

d. DoD has failed to actively investigate, and the FDA has failed to consider in its authorization the devastating negative effects that the AVA has allegedly had on the dozens of service members who have grouped together to assert claims against the manufacturer of the AVA.¹⁵

e. DoD has failed to report and the FDA has failed to investigate instances of military disability evaluation boards willfully ignoring evidence of military doctors documenting systemic chronic illnesses among anthrax vaccine recipients.¹⁶ In January 2004 a doctor at Walter Reed National Vaccine Healthcare Center stated about one such patient:

SSG Norman's life has been significantly altered due to his disability and hope for recovery is uncertain. The lack of clinical findings is discouraging and leaves his clinical providers baffled and powerless as to an effective treatment plan. His condition is not unique for us at the Vaccine Healthcare Center.¹⁷

f. DoD has failed to report and FDA has failed to investigate deaths associated with the anthrax vaccine.¹⁸

g. DoD has failed to report and FDA has failed to investigate life-threatening and deadly cardiac adverse serious and crippling neurological reactions associated with the anthrax vaccine.¹⁹

study website, has never been published because DoD has not allowed it to be released. Dr. Golomb cannot release or speak about the report herself, as it is owned by RAND, and DoD, which contracted for the study. Dr. Golomb is an Associate Professor of Medicine at University of California, San Diego, CA. Since 1999, she has also served on the Department of Veterans Affairs Research Advisory Committee on Gulf War Veterans' Illnesses. *See* <http://www1.va.gov/RAC-GWVI/page.cfm?pg=24>

¹⁴ RAND Corp., abstracts, "A Review of the Scientific Literature as It Pertains to Gulf War Illnesses" <http://www.rand.org/multi/gulfwar/publicationabstracts.html#voll>

¹⁵ *See* <http://www.sskrplaw.com/vaccine/anthrax.html>. **This Court may find noteworthy that the DoD has been held immune in this case by the “Feres” Doctrine, and the manufacturer has asserted the so-called “military contractor defense”, both of which minimize claimants’ chances of success. These roadblocks to service members seeking retrospective redress make this Court’s consideration of prospective remedies all the more important.**

¹⁶ *See, e.g.*, Declaration of Edward Norman and related medical record attachments (attached hereto and incorporated herein as Exhibit “N”).

¹⁷ *Id.*

¹⁸ *See, e.g.*, Declaration of Virginia Shemeley (attached hereto and incorporated herein as Exhibit “K”).

¹⁹ *See, e.g.*, Declaration of TSgt Lavester Brown - USAF, ret. and related attachments; and Declaration of Sgt. Bridget Savage and related attachments (attached hereto and incorporated herein as Exhibits “L” and “M” respectively).

h. DoD failed to report and FDA failed to investigate the case of a sergeant in the Air National Guard who was forced to seek “whistleblower” status under state law in order to overcome her unit’s unwillingness to provide medical care for chronic illnesses resulting from adverse reactions to the anthrax vaccine. The sergeant was eventually granted “whistleblower” status on March 30, 2001, and has been seen for extended visits at Walter Reed Army Medical Center three times over the past five years.²⁰

i. DoD has failed to report and FDA has failed to investigate instances of military physicians willfully denying chronic illnesses associated with the anthrax vaccine, even when this association has been established by experts at the Walter Reed National Vaccine Healthcare Center.²¹

Unfortunately, these troubling circumstances do not exist in a vacuum, and must be viewed within the full breadth of the controversy surrounding the military’s financial support of the suspect vaccine. The conduct on the part of DoD, HHS and FDA when dealing with the creation, financing, and continued unrelenting support for the program include the following instances:

a. The DoD Inspector General refused to investigate or refer for prosecution substantive criminal allegations against three senior military officers who: (a) gave false or misleading testimony to Congress or to a military court relating to the safety, efficacy and licensed status of AVA; and/or (b) accepted payment from the AVA manufacturer, BioPort Corp., after their retirement from the military. These allegations were submitted to the DoD Inspector General twice, most recently on March 8, 2002.²²

b. The Assistant Secretary of Defense for Health Affairs and the Deputy Director of the Military Vaccine Agency, two declarants in the instant case, have publicly stated that DoD does not experiment on its service members,²³ but have failed to disclose one or

²⁰ See March 30, 2001, correspondence from Mississippi Special Asst. Atty. General’s office to MSgt. Debbie Vick, addressing the issues (attached hereto as Exhibit “N”).

²¹ See Declaration of Chief Petty Officer Luis Hernandez and associated attachments attached hereto as Exhibit “O.”

²² These allegations were the subject of a letter from Senator Christopher Dodd (D-CT) to the DoD Inspector general on March 2, 2001; and a later letter from Senator Dodd to the Federal Bureau of Investigation pursuant to a Defense Criminal Investigative Service (DCIS) memo, “Special Interest Case: OIG Hotline No. 84-142,” dated Nov 20, 2002 (such memo is attached hereto as Exhibit “G”).

²³ Assistant Secretary of Defense for Health Affairs Dr. William Winkenwerder, press briefing, December 23, 2003 (<http://www.defenselink.mil/transcripts/2003/tr20031223-1062.html>) (“We do not do experiments on soldiers and service members. We only use licensed FDA products.”)

more Army experiments involving anthrax vaccine that resulted in service members becoming disabled.²⁴

c. The Attorney General of the United States refused to investigate alleged criminal misconduct by senior Department of Defense officials related to AVIP after a military officer personally briefed him on January 10, 2002, and then advised of the same allegations in a follow-up letter to which the Department of Justice responded on March 29, 2002.²⁵

d. The Assistant Secretary of Defense for Health Affairs, Dr. William Winkenwerder, a declarant in the instant case, refused to investigate alleged underreporting of anthrax vaccine adverse reactions after a January 14, 2002 meeting with military officers who informed him that “the failure of AVIP is the result of systemic cultural problems in military medicine.”²⁶

e. DoD has failed to investigate alleged conflicts of interest by, and the Secretary of the Army has refused to reveal financial disclosure statements for, two senior Army officers who are either directly involved in AVIP management or involved in Army anthrax vaccine research (one officer, Colonel John Grabenstein, is a declarant in the instant case).²⁷ DoD’s unwillingness to disclose the non-federal income of these two officers appears to be an attempt to exempt them from accountability for possible conflicts of interest under the DoD Joint Ethics Directive (DoDD 5500.7), DoD Joint

And if there are, for rarely used types of products, an investigational-type of use, we follow assiduously the guidelines of the FDA in performing those studies.”).

²⁴ See Declaration of Steve Turney, on behalf of his son, Matthew Turney, dated Feb 27, 2005, and associated attachments, collectively attached hereto as Exhibit “H.”

²⁵ See Declaration of Major Richard Poplin, dated Feb 27, 2005, and associated attachments, collectively attached hereto as Exhibit “I.”

²⁶ Despite being personally briefed on these issues by three military officers in a memo dated January 14, 2002 (a copy of which is attached hereto as Exhibit “R”), the Assistant Secretary of Defense for Health Affairs has continued to publicly assert that anthrax vaccine causes no long-term adverse health effects. See: ASD(HA) Dr. William Winkenwerder, DoD press briefing, Jun 28, 2002: http://www.defenselink.mil/transcripts/2002/t06292002_t0628ww.html; ASD(HA) Dr. William Winkenwerder DoD press briefing, Dec 23, 2003:

<http://www.defenselink.mil/transcripts/2003/tr20031223-1062.html>; and ASD(HA) Dr. William Winkenwerder DoD press briefing, Jun 30 2004:

<http://www.dod.mil/transcripts/2004/tr20040630-0948.html>. This is a systemic problem with the continued support for the AVIP, in that those called upon to support the program by the DoD are also called upon by the FDA to make the necessary declarations.

²⁷ See Declaration of TSgt Lavester Brown, Ex. L, and Attachment “A” thereto (Oct 26, 2004 letter to Senator Dole, pp. 16-20) for an extensive discussion of potential conflicts of interest by Army pharmacist Col John Grabenstein, a declarant in the instant case. The Department of the Army recently denied a FOIA request for information on Col. Grabenstein and Col. Carl Alving's non-federal income in an email from Mr. John Peterson, HQ MEDCOM, Department of the Army, sent on Feb 22, 2005, 3:47 p.m.

Ethics Regulation (DoDD 5500.7R),²⁸ and related federal statutes and regulations (e.g. 5 C.F.R 2635,²⁹ 5 C.F.R 2640³⁰ and 5 C.F.R . 3605.107³¹).

Petitioner mentions these items not as a proof in contradiction to the proper use of discretion for the authorization, but simply because this Honorable Court cannot decide the issues addressed herein without a full and complete appreciation for the gamesmanship that has taken place in the past (and present) with this issue, and so that the specific instances of indiscretion (reviewed in paragraphs 16-21 above) are viewed in the proper context.

Therefore, in the face of the intentionally omitted review of known and potential risks associated with the AVA, it was an abuse of discretion for the emergency use authorization to be issued.

- - - Adequate, Approved, and Available Alternatives

The BioShield Act authorization was granted as an abuse of discretion because there exists “adequate, approved, and available alternatives” to the AVA that should foreclose the authorization.³² As many recent studies have revealed, the distribution of antibiotics following an exposure to anthrax can substantially prevent a great majority of anthrax infections from

²⁸ See links at DoD Inspector General Ethics website:

http://www.defenselink.mil/dodgc/defense_ethics/ethics_regulation/

²⁹ http://www.access.gpo.gov/nara/cfr/waisidx_03/5cfr2635_03.html

5 C.F.R. 2635.802(b), Conflicting outside employment and activities. *An employee shall not engage in outside employment or any other outside activity that conflicts with his official duties.* An activity conflicts with an employee's official duties: (b) If, under the standards set forth in Secs. 2635.402 and 2635.502, it would require the employee's disqualification from matters so central or critical to the performance of his official duties that the employee's ability to perform the duties of his position would be materially impaired. Employees are cautioned that even though an outside activity may not be prohibited under this section, it may violate other principles or standards..."

³⁰ <http://www.afmc-pub.wpafb.af.mil/HQ-AFMC/JA/lo/lojaf/ethics/ogeregs/5cfr2640.htm>

³¹ http://www.access.gpo.gov/nara/cfr/waisidx_02/5cfr3601_02.html

³² See, e.g., Nass Declaration (Ex. B), at 8-15.), as well as the John Hopkins study noted below.

occurring.³³ The relative risks and benefits of antibiotics versus prophylactic immunization have been addressed by the CDC Advisory Committee on Immunization Practices. This CDC panel concluded that anthrax vaccine should be given prophylactically only for those at risk for repeated exposures to aerosolized *B. anthracis* spores through their occupation.³⁴

The court is well-versed from prior submissions of the parties as to the controversy surrounding the efficacy of the AVA itself. Over forty years of statements on anthrax vaccine efficacy undermine FDA's attempt, in the Emergency Use Authorization, to once again assert the study often referred to as "the Brachman study" has any relevance to inhalation exposure efficacy.³⁵

Therefore, in the face of these safer recognized antibiotic alternatives, it was an abuse of discretion for the emergency use authorization to be issued.

BioShield Act Does Not Override 10 U.S.C. 1107 Mandate for Informed Consent

Defendant's Emergency Motion improperly seeks to circumvent the informed consent requirements of 10 U.S.C. 1107. It is important to note that 10 U.S.C. 1107 (entitled "Notice of use of an investigational new drug or a drug unapproved for its applied use") requires that "[w]henver the Secretary of Defense requests or requires a member of the armed forces to

³³ See, e.g., the recently published study by John Hopkins School of Public Health (funded by the National Institutes of Allergy and Infectious Diseases) (http://www.jhsph.edu/PublicHealthNews/Press_Releases/PR_2004/Brookmeyer_anthrax_vaccine.html). It is also common knowledge that the victims of the anthrax attacks who were promptly treated with aggressive doses of antibiotics survived the attacks.

³⁴ Centers for Disease Control, "Use of Anthrax Vaccine in Response to Terrorism: Supplemental Recommendations of the Advisory Committee on Immunization Practices", Morbidity and Mortality Weekly Report/ 51(45);1024-1026, Nov 15, 2002 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5145a4.htm>).

³⁵ The best and most efficient way to demonstrate the undermining of this cornerstone portion of the authorization is through submission of a Summary of Statements on AVA Efficacy (attached as Exhibit "J").

receive ... a drug unapproved for its applied use, the Secretary shall provide the member with notice containing the information specified in [1107(d)].”

The two statutes at issue interact as follows: (a) an emergency use authorization does not make a drug “approved,” it simply permits its emergency use; and (b) the emergency use authorization still acts as a “request” of the service members to take the drug.³⁶ In turn, the notice requirements of 10 U.S.C. 1107(d) must still be complied with (under the statute and this Court’s October 27, 2004 ruling).

The notice requirements in 10 U.S.C. 1107(d)(3) include “[i]nformation regarding the possible side effects.” The proposed tri-fold pamphlet to be distributed to service members under the emergency use authorization does not contain accurate and complete information regarding the possible side effects of AVA. The FDA approved insert for the updated AVA in 2002 contains 7 pages (single spaced) of important guidance on the vaccine.³⁷ As noted above, the information received about possible side-effects has grown exponentially since January 2002 (as demonstrated by the thousands of VAERS complaints), and none of this information is included in the insert or the tri-fold pamphlet.³⁸

DoD officials have previously recognized that there are viable alternatives to pre-exposure mass prophylaxis with AVA. On August 10, 2001, two Undersecretaries of Defense,

³⁶ DoD's use of coercive language in the draft trifold brochure, that failure to take the vaccine may place the military mission at risk probably creates something more imposing than a "request" and something just shy of a “requirement” from commanders to take the vaccine. Even way, the requirements of 10 U.S.C. 1107 remain applicable.

³⁷ See <http://www.bioport.com/AnthraxVaccine/Insert/AVAIInsert.asp>.

³⁸ FDA's failure to publish the trifold with the authorization in the Federal Register on February 2, 2004 (even though the EUA states that the FDA had already approved it) is further evidence of the agency attempting to shield DoD from compliance with the law.

Mr. Chu and Mr. Aldridge, proposed sensible alternatives to use of anthrax vaccine in a memo to Secretary Rumsfeld.³⁹

Therefore, as the steps proposed by the Defendants to circumvent this court's October 27, 2004, ruling would act to violate the statute supporting such order, the request should be denied.

Improper Authorization Because AVA is Unapproved Product

The nature of an emergency use authorization for an "unapproved product" is different than that required for "an unapproved use of an approved product" under 21 U.S.C. §360bbb-3(e). One principal difference is that a required condition of an emergency use authorization for an "unapproved product" is to establish a system for "monitoring and reporting of adverse events associated with the emergency use of the product." 21 U.S.C. §360bbb-3(e)(1)(A)(iii).

In the present instance, these reporting requirements, appropriately implemented, would require active monitoring of recipients that would inevitably reveal the same chronic illnesses associated with AVA that are detailed in the FDA-approved package insert. Defendants have inaccurately portrayed the AVA as an "approved product." On this limited issue, Petitioners disagree with the position espoused (or accepted) by the party Plaintiffs, as Plaintiffs have unnecessarily and inappropriately conceded this issue throughout this litigation.

The AVA is not an approved product despite the fact that the FDA continues to willfully ignore that AVA was improperly licensed by the National Institutes of Health (NIH) back in the 1970's in violation of then-existing FFDCAs statutory requirements to demonstrate efficacy.⁴⁰

³⁹ See Memo from Undersecretaries of Defense (USD for Acquisition, Technology and Logistics (AT&L)) Edwin "Pete" Aldridge and Dr. David Chu (USD for Personnel & Readiness, P&R), Secretary of Defense Rumsfeld, August 10, 2001 (attached hereto as Exhibit "Q").

Based upon this improper classification of the AVA, and the defects in the authorization reflecting such misclassification, Defendants' request for relief should be denied.

Procedural Alternatives that Foreclose the “Emergency” Nature of the Motion

Petitioners believe Defendants' arguments for urgency are completely without merit and appear to be an attempt to undermine a careful deliberation of the ramifications of the Emergency Use Authorization by this Court. Since the Court's October 27, 2004 injunction, DoD has continuously had available to it two remedies that allow the immediate resumption of anthrax immunizations:

- a. Presidential waiver of informed consent pursuant to 10 U.S.C. 1107(f) and E.O. 13139, which would allow mandatory anthrax immunizations without informed consent; or,
- b. A voluntary immunization program with informed consent, in which service members would be granted the information noted above (similar to that provided postal workers and Congressional staff who were offered anthrax vaccine by the Centers for Disease Control in December 2001).⁴¹

Therefore, DoD currently has available to it alternative legal and ethical means of protecting military service members from the purported threat asserted by Deputy Secretary Wolfowitz in his December 10, 2004 letter. The only conclusion that can be garnered from the chosen

⁴⁰ See Declaration of Sammie Young and the related GAO Report B-164031(2), “Problems Involving the Effectiveness of Vaccines,” Mar. 28, 1972, pp. 12-13 attached hereto as Exhibit “S.”

⁴¹ Notably, after being provided informed consent, less than 2% of approximately 10,000 civilians offered the anthrax vaccine for post-exposure prophylaxis took the vaccine, even though they had been exposed to anthrax. See: AMedNews.com, "Risk-benefit ratio steers public health action", Jan 14, 2002 <http://www.ama-assn.org/amednews/2002/01/14/hll20114.htm>

While Petitioners acknowledge that untreated inhalation anthrax can be fatal, none of those who declined the Center for Disease Control (CDC) offer of anthrax vaccine died or became ill despite inconsistent adherence to a recommended 60-day regimen of antibiotics after exposure. See: Shepard CW, et. al., "Antimicrobial post-exposure prophylaxis for anthrax: adverse events and adherence", *Emerg Infect Dis*, Oct. 8, 2002 (<http://www.cdc.gov/ncidod/EID/vol8no10/02-0349.htm>).

approach is that the DoD fears educating its service members as to the true known and potential risks of the vaccine.⁴²

WHEREFORE, for all the foregoing reasons, Petitioners respectfully request that this Honorable Court deny Defendants' pending Emergency Motion.

⁴² This discussion compels Petitioners (and hopefully this Honorable Court) to doubt the existence of a true threat-driven emergency, as it is impossible to believe that the President of the United States would intentionally place service members' lives at risk from an accepted anthrax attack threat simply to indulge Defendants institutional resistance to fully informing the troops about the risks of anthrax vaccine, or out of fear that a Presidential waiver would have a political backlash at a later date when the true risks of the vaccine are revealed. Petitioners do not accept this as credible, given the oft-stated concern of the President for the lives and well-being of military service members, and must conclude instead that no true emergency exists.

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