

## **The safety and efficacy of anthrax vaccine have not been established, and the preponderance of the world's literature shows the vaccine is unsafe, and a contributor to Gulf War Syndrome as acknowledged in the vaccine's package insert**

When the DOD's Anthrax Vaccine Immunization Program was announced in late 1997, published evidence for both safety and efficacy of the anthrax vaccine was lacking. Dr. Peter Turnbull, formerly head of anthrax research at Porton Down, and others had made this information available in the open literature. Rodent challenge studies showed poor efficacy of the UK and US killed human anthrax vaccines against highly virulent strains, and there existed no published safety data, apart from a study of an earlier, unlicensed "Brachman" (a.k.a. "Merck") anthrax vaccine. It contained little information on systemic adverse effects.<sup>1</sup> A later, unpublished CDC 'open label' study of the licensed US anthrax vaccine, purported to affirm vaccine safety, used report forms that only collected information on local reactions. Although a nurse at the Alabama factory where the bulk of the study's anthrax vaccinations were administered had expressed concern about the adverse reactions, and these concerns were discussed at the CDC, she was overruled by the mill's doctor, and the documentary evidence suggests the matter was then dropped.<sup>2</sup>

Reports of several panels<sup>3 4 5</sup> that had been charged with investigating Gulf War Syndrome (GWS), and claimed the vaccine had nothing to do with it, were reviewed. The evidence they relied on to draw conclusions about the role of anthrax vaccine was shaky at best. The reports either cited no references to support their vaccine conclusions, or cited only briefings by military officers, not scientific studies.

Despite the finding by a Senate committee in 1994 that anthrax vaccine was being considered as a possible cause of GWS,<sup>6</sup> and the statement by the Persian Gulf Veterans Coordinating Board that "all potential causes [of GWS] that have been identified are being investigated,"<sup>7</sup> when I reviewed the full portfolio of federal research on GWS in 1999, I found that of the 166 studies listed, none looked specifically at anthrax vaccine.<sup>8</sup>

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<sup>1</sup> Brachman PS, Gold H, Plotkin SA et al. Field evaluation of a human anthrax vaccine. *Am J Pub Health* 1962;52: 632-45.

<sup>2</sup> Centers for Disease Control. Observational study of anthrax vaccine, 1967-72. Report and raw data obtained by FOIA to CDC, August 2000.

<sup>3</sup> NIH Technology Assessment Workshop Panel. The Persian Gulf Experience and Health. *JAMA* 1994;272:391-6.

<sup>4</sup> Institute of Medicine Medical Follow-Up Agency. Health Consequences of Service During the Persian Gulf War. National Academy Press. Washington DC. 1995.

<sup>5</sup> Report of the Defense Science Board Task Force on Persian Gulf War Health Effects. June 1994. <http://www.gulfink.osd.mil/dsbrpt/>

<sup>6</sup> Senate Committee on Veterans' Affairs. Is military research hazardous to veterans' health? Lessons spanning half a century. December 8, 1994. S. Prt. 103-97. <http://www.gulfweb.org/bigdoc/rockrep.cfm>

<sup>7</sup> Persian Gulf Veterans Coordinating Board. Unexplained illnesses among Desert Storm veterans. A search for causes, treatment, cooperation. *Arch Intern Med* Feb 13, 1995; 155:262-8.

<sup>8</sup> Research Working Group of the Persian Gulf Veterans Coordinating Board. The Annual Report to Congress: Federally Sponsored Research on Gulf War Veterans' Illnesses for 1998, Appendices. Department of Veterans Affairs. June 1999. pp 7-13. *This list of studies is provided to the Inquiry.*

Only because the Wessely/Unwin study was designed to investigate all potentially noxious exposures that GW soldiers had faced, had data on anthrax vaccine been captured.

The low rate of GWS in French troops, who were unvaccinated, had used prophylactic doxycycline and consumed cleaner, bottled water, needed explanation. The issue of whether small numbers of French troops who did develop GWS were in liaison positions, and were vaccinated alongside US and UK units, has been raised by the French Ministry of Defense, but has not been resolved.<sup>9</sup>

Numerous vaccinated but nondeployed Gulf War 'era' soldiers in the US have developed similar multisystem illnesses as the deployed soldiers. Dr. Lea Steele was able to analyze this intriguing finding in a study of Kansas Gulf War veterans.<sup>10</sup> She found that nearly 4% of the veterans who had not been deployed, nor vaccinated in preparation for deployment, met her GWS case definition. (She later concluded that this number is approximately the prevalence rate of a similar condition in civilians.) But those who were vaccinated in preparation for deployment, but never actually deployed, had a rate 3 times higher, nearly 12%.

The US Institute of Medicine (IOM) committee on GWS under Dr. Harold Sox was asked to review only published, peer-reviewed literature, and did a credible job looking at the published literature on anthrax vaccine. In September 1999 the committee concluded that no evidence existed to either support or refute anthrax vaccine as a cause of chronic adverse health effects, including GWS.<sup>11</sup> (Since then, a 2003 Cochrane review of anthrax vaccines drew the same conclusion: "Further research should be carried out on the short and long term safety effects of available vaccines and if possible their effectiveness."<sup>12</sup>)

However, the IOM committee overlooked several studies that linked anthrax vaccine to GWS. The first study was performed by a contractor to the Canadian Department of National Defense (DND), Goss-Gilroy, and was published on the DND website in 1998.<sup>13</sup> The study used self-reports (as nearly all the GWS studies have done) and found that immunization with biological warfare vaccines, which for Canadian troops included only anthrax and plague vaccines, was associated with chronic fatigue.

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<sup>9</sup> French to Check Liaison Officers for Gulf Syndrome. Reuters (Paris) Sept. 14, 2000.

<sup>10</sup> Steele L. Prevalence and patterns of Gulf War illness in Kansas veterans: association of symptoms with characteristics of person, place, and time of military service. *Am J Epidemiol.* 2000 Nov 15;152(10):992-1002.

<sup>11</sup> Institute of Medicine. *Gulf War and Health: Volume 1. Depleted Uranium, Sarin, Pyridostigmine Bromide, and Vaccines 1999.* National Academies Press, Washington DC. p313.

<sup>12</sup> Jefferson T, Demichelli V, Deeks J et al. Vaccines for preventing anthrax (Cochrane Review). In: *The Cochrane Library*, Issue 2, 2003.

<sup>13</sup> Goss-Gilroy. Study of Canadian Gulf War Veterans. Never published except on the DND website. [http://www.dnd.ca/menu/press/Reports/Health/health\\_study\\_eng\\_1.htm](http://www.dnd.ca/menu/press/Reports/Health/health_study_eng_1.htm) (could NOT be accessed August 28, 2004)

Chronic fatigue was a cardinal feature of GWS, as defined by the CDC in a seminal paper by Fukuda et al in 1998.<sup>14</sup>

In January 1999 a groundbreaking paper by Unwin and Wesseley et al in *The Lancet* showed that anthrax vaccine was associated with development of a GWS syndrome, defined by the authors, in both veterans of the Gulf War, and also in a small number of anthrax-vaccinated veterans of the Bosnia conflict.<sup>15</sup> Because of the large number of veterans studied, and good statistical techniques, this research is very convincing. It furthermore showed that multiple vaccinations were independently associated with development of GWS.

In 1999, Colonel John Grabenstein, an army pharmacist who had just completed a PhD in Pharmacoepidemiology, was chosen to serve as the clinical head and deputy director of the anthrax vaccine program agency. He was charged with supervising a portfolio of Army research to show the anthrax vaccine was as safe and effective as DOD had reported to Congress. Col. Grabenstein was also a consultant and trainer for Merck and Glaxo Smith Kline, and chaired a committee of the American Pharmacists' Association whose purpose was to train pharmacists to prescribe and administer vaccines without a doctor's prescription, and to pass legislation needed for them to do so in every state. He is on the Board of the Immunization Action Coalition, an industry-sponsored advocacy organization. Col. Grabenstein has written to pharmacists, "At present, about 50 serious vaccine-associated injuries occur each year in the United States, in the course of protecting a population of 275 million into which 3.9 million children are born annually."<sup>16</sup>

Yet the FDA says that 15% of 12,000 *reported* yearly reactions are serious. His remarkable ability to spin even the worst news has led to his promotion to clinical chief and spokesperson for all military vaccinations. As quoted in the Washington Post, "Grabenstein said vaccinations of 524,000 military personnel had found only low risks such as sore arms, aches and fevers, with the rare serious reaction for 1 in 100,000."<sup>17</sup> Grabenstein was quoted in the NY Times on December 21, 2001 as saying, "If people are getting sick, it is not due to the [anthrax] vaccine." He has misrepresented the conclusions of a number of other studies of anthrax vaccine, claiming that eighteen studies prove the anthrax vaccine to be safe. He also worked closely with the Institute of Medicine committee that produced the March 2002 report "The Anthrax Vaccine: Is It Safe? Does It Work?"<sup>18</sup> He is thanked in the report's acknowledgments.

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<sup>14</sup> Fukuda K, Nisenbaum R, Stewart G et al. Chronic multisymptom illness affecting Air Force veterans of the Gulf War. *JAMA* 1998;280:981-8.

<sup>15</sup> Unwin C et al. Health of UK servicemen who served in the Persian Gulf War. *The Lancet* 1999; 353:169-178.

<sup>16</sup> Grabenstein J and Wilson JP. Are vaccines safe? Risk communication applied to vaccination. *Hospital Pharmacy* 1999;34:713-729.

<sup>17</sup> Vaccine offer raises new questions. *Washington Post*, December 23, 2001. p A20.

<sup>18</sup> Institute of Medicine. *The Anthrax Vaccine: Is it safe? Does it work?* National Academy Press 2002. Washington DC.

This report, cited repeatedly by FDA in its earlier, grossly flawed version of a final rule, is a cynical whitewash of the safety and efficacy concerns about anthrax vaccine, and makes a number of unsubstantiated and incorrect claims regarding both.<sup>19 20</sup>

Furthermore, the report acknowledges the DOD's Defense Medical Surveillance System database's findings of a statistical association between immunization with anthrax vaccine and later hospitalizations for diabetes, breast cancer, asthma, Crohn's Disease, thyroid cancer and multiple sclerosis. It notes that these associations could be signals of a possible causal relationship, especially for diabetes, Crohn's Disease and multiple sclerosis, and recommends "additional follow-up" in the text. However, when the report makes its final recommendations, it recommends *against* such follow-up, saying, "DOD should develop systems to enhance the capacity to monitor the occurrence of later-onset health conditions that might be associated with the receipt of any vaccine; the data reviewed by the committee do not suggest the need for special efforts of this sort for AVA."

The National Academy of Sciences division in which this report was produced is the Medical Follow-Up Agency, and it is 100% funded by the Department of Defense and the Department of Veterans Affairs. Would this division have retained its funding had the report provided an honest assessment of the vaccine?

Under Col. Grabenstein's oversight, the army has published at least four studies purporting to show anthrax vaccine is safe and effective.<sup>21 22 23</sup> However, the data reported in these studies leave much to be desired. The most important study, the only one designed to evaluate long-term reactions, was conducted on 603 vaccinated medical staff at Tripler Army Medical Center.<sup>24</sup> According to the principal investigator, "The objectives were to provide active surveillance of self-reported side effects and the duration of symptoms."<sup>25</sup> Soldiers were asked to complete a questionnaire about symptoms that developed after their last anthrax vaccination, whenever they presented for a subsequent inoculation, or within two weeks of vaccination.

One case of multiple sclerosis and two other neurologic reactions developed in vaccinees. One neonatologist developed a tremor and upper extremity weakness associated with a CPK level over 1000. A pediatric cardiologist developed numbness and fasciculations, suggesting a brachial plexopathy, which resolved. Although the study was designed and

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<sup>19</sup> Nass M. Trampling on the science. [http://www.redflagsweekly.com/nass/2002\\_march11.html](http://www.redflagsweekly.com/nass/2002_march11.html)

<sup>20</sup> Schumm W, Webb FJ, Jurich AP et al. Comments on the Institute of Medicine's 2000 Report on the safety of anthrax vaccine. *Psychol Rep* 2002;91:187-91.

<sup>21</sup> Lange JL, Lesikar SE, Rubertone MV, Brundage JF. Comprehensive systematic surveillance for adverse effects of anthrax vaccine adsorbed, US Armed Forces, 1998-2000. *Vaccine*. 2003 Apr 2;21(15):1620-8.

<sup>22</sup> Rehme PA, Williams R, Grabenstein J. Ambulatory medical visits among anthrax-vaccinated and unvaccinated personnel after return from southwest Asia. *Mil Med*. 2002 Mar;167(3):205-10.

<sup>23</sup> Wiesen AR, Littell CT. Relationship between prepregnancy anthrax vaccination and pregnancy and birth outcomes among US Army women. *JAMA*. 2002 Mar 27;287(12):1556-60.

<sup>24</sup> Wasserman, G, Grabenstein JD, et al. Analysis of adverse effects after AVA in US army medical personnel. *J Occ Envir Med* 2003;45:222-233.

<sup>25</sup> Wasserman G. Tripler Army Medical Center Survey. First Annual Department of Defense Conference for Biological Warfare Defense Immunizations. Fort Detrick, Maryland. May 26, 1999. transcript.

initially advertised to seek persisting adverse reactions, the forms completed by soldiers only specified whether reactions lasted brief periods less than 72 hours, or more than 72 hours, and the published paper provides no tables on side effect duration. The paper notes that only local reactions could be linked to vaccination, and appears to dismiss vaccine causality for other reactions without providing a rationale for doing so. The exit questionnaire used was a general health questionnaire (Health Enrollment Assessment Review Survey), rather than a questionnaire designed to capture specific information related to vaccine adverse effects and their duration. In fact, the questionnaire used made no reference to anthrax vaccine.

Other problems with this study include the fact that although 603 persons were enrolled and originally reported on,<sup>26</sup> the published paper lists only 601 subjects. The abstract notes that localized reactions occurred more often in women, but neglects to mention that systemic reactions did also, at approximately twice the rate of men. Although the published paper notes that one reason for enrollees to drop out was pregnancy, it omits mention that eleven women became pregnant during their vaccine series, and the outcome of these pregnancies remains unknown.

This is important because navy physician Cdr. Megan Ryan has found that women vaccinated for anthrax during the first trimester have a higher rate of birth defects in offspring than unvaccinated women.<sup>27 28</sup> Apparently this research was compelling enough, despite an army study to the contrary, for the FDA in 2002 to change the pregnancy warning on the vaccine label from a C (no data on risk) to a D (data suggests increased risk during pregnancy). However, the data have not yet been published.

Dr. Maria Araneta, also associated with the Naval Health Research Center and University of California, has shown that GW veterans are also likelier than controls to have children with certain birth defects.<sup>29</sup>

According to the Tripler study authors, “Women in the immunized cohort were more likely to report (in their exit questionnaire) that their general health was ‘poor or fair’ compared with the unimmunized cohort (RR 4.4; 95% CI: 1.3-15.1)...otherwise there were no notable trends or associations.” Regarding the Tripler authors’ claim that there were no notable trends in their data, one would think that the high female reaction rates and poorer female health at the study’s conclusion would be notable, and that a serious neurologic reaction rate of 0.5% in a vaccine study should have raised some eyebrows.

Because all the army studies claim to show the vaccine is safe, sometimes in spite of evidence to the contrary, and all were supervised by the same individual, Colonel

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<sup>26</sup> GAO/T-NSIAD-99-226

<sup>27</sup> MMWR 127 vol 51 No. 6. Notice to Readers: Status of US Department of Defense preliminary evaluation of the association of anthrax vaccination and congenital anomalies.

<sup>28</sup> Johannes L. Anthrax Vaccine May Increase Incidence Of Birth Defects For Pregnant Women. Wall Street Journal. January 16, 2002.

<sup>29</sup> Araneta MRG, Schlangen KM, Edmonds LD et al. Prevalence of birth defects among infants of Gulf War veterans in Arizona, Arkansas, California, Georgia, Hawaii and Iowa, 1989-93. Birth Defects Res Part A. Clin Mol Teratol 2003; 67: 246-60.

Grabenstein, while all the research done elsewhere has found that chronic illnesses are associated with anthrax vaccinations, an unbiased review is forced to disregard the army research.

Several years ago, in conjunction with the *Hartford Courant* newspaper, I reviewed the first 1660 anthrax vaccine adverse events reports to FDA (found in the Vaccine Adverse Effect Reporting System (VAERS)), and found that about 160 met the CDC's case definition for GWS. Most of those reporting had not been to the Gulf. They had reported at least two of the following three problems: musculoskeletal pain, fatigue, and a cognitive or emotional disorder. I wrote to the FDA about this, and enclosed the Fukuda/CDC's case definition from the *JAMA*. I was later gratified to learn that the revised January 2002 anthrax vaccine package insert<sup>30</sup> includes the CDC's GWS case definition in the list of reported adverse reactions, although the fact that this is the GWS definition is not stated.

As early as May 1999, 14 months after the start of the Anthrax Vaccine Immunization Program, a group of military clinicians got together to identify illnesses developing after anthrax vaccination, develop criteria for waiving further vaccinations in certain ill individuals, and develop evaluation, prevention and treatment strategies. Col. Grabenstein later joined this group, which placed him in the interesting position of denying that chronic illnesses are caused by anthrax vaccine, while also coauthoring credible reports of vaccine adverse reactions, and coauthoring clinical guidelines for vaccine-related disorders. The guidelines have undergone several revisions since 1999, and can be found on the DOD website.<sup>31</sup>

It is interesting that the unexpected reactions seen by these military clinicians in 1999, when they wrote the first draft of the guidelines, remain important and continue to be addressed by the guidelines four years later: these include neurological reactions, chronic fatigue, chronic pain syndromes and 8<sup>th</sup> nerve dysfunction, among others.<sup>32</sup>

One of the clinicians in the forefront of responding to illnesses that develop following military vaccinations is Col. Renata Engler, MD, the Army's chief allergist-immunologist. She evaluated severely affected soldiers at Walter Reed from the beginning, and founded the National Vaccine Healthcare Center in 2001.<sup>33</sup> Subsequently the military's Vaccine Healthcare Network has expanded to four sites, and its mission has expanded to include illnesses developing after any vaccination. The centers have also treated smallpox vaccine reactions, and developed screening criteria for waiving both anthrax and smallpox vaccinations. They are involved in research on vaccine reactions. Over 1,000 in depth case reviews and patient evaluations have been performed. Despite the centers' successes, funding was about to be cut off in October 2004, but has been reinstated for one year as a result of Congressional interest.

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<sup>30</sup> <http://www.fda.gov/cber/label/biopava0131022LB.pdf>

<sup>31</sup> [http://160.151.186.52/VHC/providers\\_management.htm](http://160.151.186.52/VHC/providers_management.htm).

<sup>32</sup> *Copies of the 1999 and 2003 guidelines are provided for the inquiry.*

<sup>33</sup> <http://www.ha.osd.mil/afeb/meeting/051104meeting/Transcript%20-%20May%2011%202004.pdf>

According to Walter Reed National Vaccine Healthcare Center authors,<sup>34</sup> “between May 1998 and July 2001, 82 patients were evaluated for complaints of prolonged systemic clinical problems whose onset was associated or attributed to anthrax vaccine exposure by the patient, referring provider or family member...the spectrum of systemic symptoms in this group is heterogeneous with the reasons for referral including (but not limited to) one or more of the following features: non-injection site skin rashes (15%); persistent headaches (12%); tinnitus (16%); other neurologic disease or symptoms (21%); prolonged fatigue with 50% functional loss for > 60 days (21%). Specific diagnoses are diverse with some patients manifesting prolonged disability...there continues to be a need to improve our understanding of these clinical scenarios.”

In February of this year, Army Surgeon General James B. Peake issued new guidelines for treatment of soldiers’ illnesses that do not respond to standard treatments.<sup>35</sup> He suggested that vaccine reactions be considered, that vaccine histories be taken, and that clinicians seek second opinions from the vaccine healthcare centers. His memo followed publicity about the death of Rachel Lacy, a 22 year old nursing student and army reservist who was called up for duty in Iraq, given five vaccines in one day, including anthrax and smallpox, rapidly became ill, and died 4 weeks later at the Mayo Clinic. Her autopsy revealed adult respiratory distress syndrome and eosinophilic lymphocytic myocarditis. Another military case of eosinophilic lymphocytic myocarditis was seen at Mayo Clinic around the same time, also associated with five vaccines including anthrax and smallpox, but the soldier lived to have an endomyocardial biopsy, receive high dose prednisone treatment, and recover.<sup>36</sup>

The Surgeon General may also have been responding to media reports of over twenty “mystery pneumonias” in soldiers that were non-infectious, associated with eosinophils in blood or bronchoalveolar lavage fluid, and resulted in a number of ventilator cases and several deaths.

After years of military physicians failing to report vaccine adverse reactions to FDA, and failing to acknowledge in the patients’ medical records that such reactions have occurred, the Vaccine Healthcare Centers have begun to reverse this unfortunate trend. One soldier who I recently evaluated had been extensively worked up by the Vaccine Healthcare Center. His record there stated,

*“Staff Sergeant \*\*\*\*\* was a high functioning, decorated service member prior to beginning the anthrax vaccine in 1998. He has had no disciplinary action. He has functioned well in his duty assignments and is highly regarded even now. Staff Sergeant \*\*\*\*\*’s life has been significantly altered due to his current disability, and hope for*

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<sup>34</sup> Martin BL, Nelson MR, Labutta R et al. Anthrax Vaccine Temporally Associated Systemic Adverse Events Referred to a Tertiary Medical Center. Abstract presented at the 58<sup>th</sup> annual meeting American Academy of Allergy Asthma and Immunology, March 2002. Supplied by National Vaccine Healthcare Center at Walter Reed Army Medical Center.

<sup>35</sup> <http://www.anthrax.osd.mil/media/pdf/LearningfromAdverse.pdf> His memo is enclosed for the Inquiry.

<sup>36</sup> Murphy JG, Wright RS, Bruce GK, Baddour LM, Farrell MA, Edwards WD, Kita H, Cooper LT. Eosinophilic-lymphocytic myocarditis after smallpox vaccination. Lancet. 2003 Oct 25;362(9393):1378-80.

*recovery is uncertain. The lack of clinical findings is discouraging and leaves his providers baffled and powerless as to an effective treatment plan. His condition is not unique for us at the Vaccine Health Care Center. We have treated many proficient service members with debilitating conditions that cannot be diagnosed or medically substantiated, conditions that have developed in close temporal association to having received the anthrax as well as other vaccines. Hopefully future medical research and discovery will provide some definitive answers to these perplexing medical dilemmas and allow us to effectively treat individuals such as Staff Sergeant \*\*\*\*\*.”<sup>37</sup>*

This statement was signed by Limone C. Collins, MD, director of the Walter Reed Regional Vaccine Health Care Center and by Jeannette F. Williams, FNP, case manager, on January 14, 2004. It is gratifying to finally have these clinicians, who see the greatest number of patients with post-vaccine illnesses, acknowledge that they too are baffled by patterns of symptoms in *many* patients who are debilitated and treatment resistant, and who have developed undiagnosable illnesses following vaccinations, usually anthrax alone or in combination with other vaccines.

Regarding the short-term adverse effects of recent anthrax vaccinations in the UK, in soldiers vaccinated before the recent Gulf deployment, two small studies have been done. The UK vaccine is given as a four dose series over one year, with yearly boosters; the US vaccine is given in 6 doses over 18 months, with yearly boosters.

In the first paper by Hayes and World, 129 soldiers working in a military field hospital were offered vaccine, and 76% (98 soldiers) accepted and began the series.<sup>38</sup> Initially, 63% had adverse reactions. “Forty-five percent of these caused incapacity.” Approximately 22% of reactors had arm pain that prevented lifting or driving for 48 hours. Twenty-one percent of reactions were designated severe. Only 27 of the 98 soldiers who began the vaccinations completed the four dose series. The authors noted, “Although the old vaccine is considered safe, the number of adverse reactions and incapacity reported by a military medical unit was unexpected.”

The second paper looked at vaccine acceptance and adverse reactions in personnel at five RAF bases.<sup>39</sup> “Those completing the [vaccine] course as a percentage of those starting it varied from 22% at base 2 to 3.7% at base 4.” Yet these authors reported that only 11% of vaccinees had side effects, and that these were mild.

Neither set of authors was able to explain the dropoff in vaccine uptake. Both studies were supported by the MOD.

In conclusion, for the FDA to assume the anthrax vaccine is safe, it would need to find a body of reliable, reproducible medical studies to refute the plethora of evidence I have

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<sup>37</sup> A copy of this soldier’s evaluation is included for the inquiry.

<sup>38</sup> Hayes SC and World MJ. Adverse reactions to anthrax immunisation in a military field hospital. J R Army Med Corps. 2000 Oct;146(3):191-5.

<sup>39</sup> Enstone JE, Wale MCJ, Nguyen-Van-Tam, JS et al. Adverse medical events in British service personnel following anthrax vaccination. Vaccine 2003; 21:1348-54.

just summarized. They do not exist. The so-called safety study overseen by the CDC from approximately 1967-1972 made no attempt to identify, quantify or follow systemic adverse vaccine reactions. It is therefore of no value in establishing vaccine safety. Anthrax vaccine must be considered a dangerous vaccine, whose benefit remains to be established. Given the fact that no reliable evidence has been provided by the US government of a risk to troops or civilians from anthrax, and given that the efficacy of this vaccine to an inhalation challenge with virulent strains of anthrax remains to be demonstrated, the risk/benefit equation for this vaccine can only be calculated as No Justification for Use.

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December 29, 2004