

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
Brachman, et.al., <i>Am. Jnl. of Hygiene</i> , p. 14. ² (Dec 1960)	Dr. Walter Schumm ³ Decl., Atch A, Ms., p. 7, et.seq. (Apr. 7, 2004)	NO	“If the incidence of anthrax in the vaccinated group (0/150) is compared with that in the inoculated controls (4/150), an apparent difference is evident ($x^2 = 4.4$, $P < 0.5$). However, if only the job categories which are associated with a high risk of developing anthrax are studied, then no conclusion with respect to the effectiveness of the vaccine can be drawn , as shown in table 4.” (emphasis added)
Brachman, et.al., <i>Am. Jnl. of Hygiene</i> , p. 20. ⁴ (Dec 1960)	Schumm Decl., Atch A, Ms., p. 7, et.seq. (Apr. 7, 2004)	NO	“ The efficacy of the anthrax cell-free antigen as a vaccine was not fairly tested in this epidemic. Although none of the 9 cases occurred in vaccinated individuals, only approximately one fourth of the employees had received the vaccine. There was an apparent difference in attack rates between workers who received placebo inoculations and those who received vaccine, but analysis of their job categories suggested that the vaccinated group was not at as high a risk as the placebo or uninoculated control groups. (emphasis added)

¹ With one exception, statements below are limited to those by employees of Defendants FDA, DoD, and HHS; to reports by the National Academy of Sciences Institute of Medicine; and to the manufacturers (MDPH, MBPI, and BioPort).

² Brachman, et.al., “An Epidemic of Inhalation Anthrax. II. Epidemiology”, *Am. Jnl. of Hygiene* (Dec 1960), Vol. 72, p. 6-23.

³ The Court may find noteworthy that despite Defendants’ disparagement of Dr. Schumm (Colonel, USAR, ret.), he has since published two papers based on his declaration in the peer-reviewed journal *Medical Veritas*. Links to abstract of these two articles are list below. Copies will be provided on request.

W.R. Schumm, R.L. Brenneman, “How “adequate and well-controlled” was the “clinical trial” of a human anthrax vaccine, 1955-1959?”, *Medical Veritas* (2004), Vol. 1, No.2, p. 166-170.

<http://www.vaccineveritas.com/images/00022.pdf>

W.R. Schumm, R.L. Brenneman, “A statistical reanalysis of Brachman et al.'s 1962 study of a human anthrax vaccine”, *Medical Veritas* (2004), Vol. 1, No.2, p. 171-178.

<http://www.vaccineveritas.com/images/00023.pdf>

⁴ Brachman (Dec 1960), Id.

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Brachman, et.al., <i>Am. Jnl. of Hygiene</i> , p. 21. ⁵ (Dec 1960)	Schumm Decl., Atch A, Ms., p. 7, et.seq. (Apr. 7, 2004)	NO	"Anthrax vaccine containing alum-precipitated protective antigen appeared to afford protection to those who received it, but this impression could not be confirmed statistically. Previous inapparent infection...also may have protected some of the workers." (emphasis added)
Brachman, et.al., <i>American Journal of Public Health</i> . ⁶ (Apr 1962)	FDA Final Rule, 69 Fed. Reg. 259, 265; Ref. 1. (Jan. 5, 2004)	YES (AR 601-615) (AR 3732-3745)	" The statistical analysis of the data indicates that the vaccine was effective in protecting against cutaneous anthrax infections. When inhalation anthrax is considered, the limited experience with this form of the disease makes the data less significant in showing effectiveness of the vaccine. " (emphasis added)
Dr. Margaret Pittman, ⁷ NIH Memorandum. Ref. No. 67-70 (Feb. 6, 1969)	Schumm Decl., p. 6 and Atch D. (Apr. 7, 2004)	YES (AR 3634) (AR 4018)	" The lack of cases of anthrax in an uncontrolled population of approximately 600 persons in the Talladega mill can hardly be accepted as scientific evidence for efficacy of the vaccine... We do not question that there might be up to 10 cases of expected anthrax per 600 workers, but without evidence of actual exposure in this mill during this time, and the apparently unpredictable incidence and distribution of anthrax in various mills (see Fig. 1, Brachman et.al. <i>Am. J. Pub. Hlth</i> 52:632, 1962) [<i>...end of sentence redacted by Defendant FDA...</i>]." (emphasis added)

⁵ Brachman (Dec 1960), Id.

⁶ Brachman, et.al., "Field Evaluation of a Human Anthrax Vaccine", *American Journal of Public Health* (Apr 1962), Vol. 52, p. 632-645 (at p. 643).

⁷ Dr. Margaret Pittman, Ph.D., was a career vaccine regulator. She was later selected to serve as the sole "consultant" to the FDA expert review panel that met from 1973-1979 and which ultimately drafted a final report that became the 1985 Proposed Rule. (AR 11)

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U. P. Kokko, CDC, memorandum to R. Murray, Director, Division of Biologic Standards, NIH. (Jan. 22, 1969)	NO	YES (AR 3752-3760)	“ There have been no controlled evaluation studies with the Michigan anthrax product as was done by Dr. Phillip Brachman using the Merck, Sharp and Dohme product.” ⁸ (emphasis added)
Dr. M. Pittman, NIH memorandum to S. Gibson, Assistant Director for Licenses and Inspections, NIH (Feb.10, 1969)	Schumm Decl., p. 6-7 and Atch E. (Apr. 7, 2004)	YES (AR 3633) (AR 4019)	“ ...Michigan [MDPH] has filed with the Division all required information and material for license except the results of an adequately controlled clinical investigation that establishes efficacy. No cases of anthrax have occurred among vaccinees. Laboratory data have been submitted that show that the product does have specific ability to protect guinea pigs. Therefore, it is recommended that license be granted and that NCDC (IND-180) be requested to obtain data with a view to determine human efficacy of the product. ” (emphasis added)

⁸ **While Defendant FDA has now selectively chosen to view Defendant DoD as a manufacturer of anthrax vaccine, FDA has previously asserted just the opposite.** The Court should carefully note the contemporaneous distinction made by NIH regulators between the “Michigan anthrax product” (i.e. AVA) and the Brachman study’s “Merck, Sharp and Dohme product.” FDA’s expert review panel also made this distinction in its 1985 Proposed Rule. Defendant FDA has attempted to erase this important distinction in its Final Rule by asserting “the vaccine used in the Brachman study was not manufactured by Merck Sharpe & Dohme, but...was provided to Dr. Brachman by Dr. G. Wright of Ft. Detrick, U.S. Army, DoD (Ref. 1).” Plaintiffs have no way to confirm or deny the FDA’s Final Rule assertion about the origin of the Brachman study vaccine. Plaintiffs note, however, the curious timing of such a discovery by Defendant FDA, arriving only when the scientific validity of the Brachman study is central to their assertion of the legality of their Final Rule. However, in testimony before Congress in October 1999 FDA asserted the agency had no control over DoD’s use of anthrax vaccine because FDA only regulated manufacturers. Then, FDA asserted that DoD was not a manufacturer. In a lengthy colloquy between U.S. Rep. Christopher Shays (R-CT) and Dr. Kathryn Zoon, then-director of the FDA’s vaccine (CBER) division, in Oct 1999, Dr. Zoon contended that since DoD was an end user and not a manufacturer, then it was not subject to regulation by FDA. See “Defense Vaccines: Force Protection Or False Security?”, Serial No. 106–130, Committee On Government Reform, House Of Representatives, 106th Congress (Oct. 12, 1999) at 123, 126, 128 of transcript (PDF). (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_hearings&docid=f:65604.pdf).

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<p>M. Pittman memorandum to S. Gibson, Assistant Director, Licenses and Inspections, NIH. (Sep.30, 1969). [referring to pre-licensure testing of the Michigan vaccine]</p>	<p>Schumm Decl., p. 7 and Atch F. (Apr. 7, 2004)</p>	<p>YES (AR 3630) (AR 4020)</p>	<p>“The recent information submitted by NCDC and Ft. Detrick for DBS IND-180 was discussed. It was emphasized that the epidemiological study did not provide control data, whereby the effectiveness of the vaccine could be evaluated. The fact that the vaccine has been used in a number of textile mills and that there has been no cases of Anthrax was substantive but not conclusive evidence of efficacy.” (emphasis added)</p>
<p>Michigan Department of Public Health⁹, submission to FDA expert review panel, p. 6. (May 1, 1973)</p>	<p>Schumm Decl., p. 8 and Atch G. (Apr. 7, 2004)</p>	<p>YES (AR 3290-3302)</p>	<p>“Analysis by the Center for Disease Control of one field trial of an earlier lot of this antigen in man, occupationally at risk of contracting anthrax, has indicated 92% effectiveness in prevention of cutaneous anthrax. Because of the infrequency of human inhalation of [sic] anthrax, it is not possible at this time to provide a quantitative estimate of the efficacy of the MDPH vaccine in conferring protection in man against either form of the disease.” (emphasis added)</p>

⁹ While MDPH (and BioPort) are not defendants in the instant case, FDA’s 2004 Final Rule infers that DoD is, and has been, the de facto manufacturer. This contention is amplified by MDPH’s 1973 submission to the FDA expert review panel, which states (at page 7): “Summary: Anthrax vaccine was developed under special impetus and financial support from both the U.S. Army Biological Laboratories, Ft. Detrick, Md. And the Investigational Vaccines Program of the Center for Disease Control.” Therefore, it is appropriate to consider MDPH’s statement(s) as a statement by the Defendant, since the documentary record suggests MDPH pre-coordinated its submissions with FDA with Defendant DoD, and that FDA to DoD deferred its regulatory responsibilities for inspections from 1970-1993.

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FDA expert review panel, final report. ¹⁰ (Aug. 2, 1979)	Not cited	YES (AR 337)	“The best evidence for the efficacy of anthrax vaccine comes from a placebo controlled field trial conducted by Brachman (Ref. 1)... 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)
FDA expert review panel, final report. (Aug. 2, 1979)	Not cited	YES (AR 338)	“ Anthrax vaccine poses no special problems other than the fact that its efficacy against inhalation anthrax is not well documented... ” (emphasis added)
AVA FDA-approved Package Insert, p. 1-2. (Dec. 1979)	Pl. Compl., para. 9. (Mar. 18, 2003) Pl. Amend. Compl., Para 17. (Jan. 6, 2004)	NO	NONE (i.e. There is no statement on efficacy at all.)

¹⁰ The expert panel submitted this report to FDA in August 1979 (AR 26). FDA made the report available to the public (but did not publish it) in 45 Fed. Reg. 77134, (Nov. 21, 1980) (AR 1). Dr. P.S. Brachman, lead author of the late-1950’s Brachman study (1960, 1962) is listed as an expert who was permitted to express views to the FDA expert review panel during its deliberations. (AR 11-12). Therefore, it is unclear how the FDA expert review panel could have been mistaken about the efficacy findings of the Brachman studies. Further, six years elapsed between the expert panel submitting their Final Report and FDA publishing the 1985 Proposed Rule, allowing adequate time for the agency to query Brachman and the expert panel to clarify the efficacy findings of the Brachman study. FDA’s belated repudiation of the efficacy findings of their own expert panel (“FDA does not agree with the Panel report...”, FDA Final Rule, 69 Fed. Reg. 259) is, therefore, unsupported by the documentary record, and constitute an “arbitrary and capricious” act of regulatory discretion and an act of “bad faith” warranting judicial intervention.

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Department of the Army, Request for Proposals (“RFP”) No. DAMD17-85-R-0078	Pl. Compl., para. 12. (Mar. 18, 2003) Pl. Amend. Compl. Para 20. (Jan. 7, 2004)	NO	“There is an operational need to develop a safe and effective product which will protect US troops against exposure from virulent strains of <i>Bacillus anthracis</i> . There is no vaccine in current use which will safely and effectively protect military personnel against exposure to this hazardous bacterial agent. ” (emphasis added)
FDA expert review panel, Proposed Rule, 50 Fed. Reg. 51005. (Dec. 13, 1985)	Not cited	YES (AR 1174-1290)	“It has become generally understood that a successful and acceptable vaccine must be: (1) Safe and (2) effective... ... Efficacy implies a useful degree of clinical protection...It is the clinical trial, however, which must provide the final critical assessment of the efficacy and safety of the new vaccine.” (emphasis added)
FDA expert review panel, Proposed Rule, 50 Fed. Reg. 51059 (Dec. 13, 1985)	Pl. Amend. Compl. Para 23. (Jan. 7, 2004)	YES (AR 1174-1290)	“The vaccine manufactured by the Michigan Department of Public Health has not been employed in a controlled field trial. A similar vaccine prepared by Merck, Sharpe & Dohme for Fort Detrick was employed by Brachman [Ref. 1] in a placebo-controlled field trial in mills processing imported goat hair. This vaccine appeared 93 percent protective against cutaneous anthrax. No meaningful assessment of its value against inhalation anthrax is possible due to its low incidence.” (emphasis added)
AVA FDA-approved Package Insert, p. 1-2. (Oct. 1987)	Not cited	NO	“Anthrax Vaccine Absorbed is used in man to promote increased resistance to <i>Bacillus Anthracis</i> by active immunization (1,2).”

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Secretary of the Army M.P.W. Stone, indemnification memo (Sep. 3, 1991)	Not cited	NO	<p>“The obligation assumed by PRI¹¹ under this contract involves unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the anthrax vaccine. These concerns stem from: a) the limited use of the vaccine to date, i.e., tests prior to approval of a vaccine by the Food and Drug Administration are on too small a scale to permit accurate assessments of types and severity of adverse reactions (only widespread use can provide this assessment;) and b) insufficient experience in mass immunization programs to truly evaluate the efficacy of the vaccine. Moreover, there is no way to predict whether the pathogen against which the vaccine may be used will be sufficiently similar to the pathogen used in tests to ensure vaccine efficacy.” (emphasis added)</p>
Dr. Bruce Ivins, et.al., <i>Infection and Immunity</i> . ¹² (Feb 1992)	Not cited	NO	<p>“Although epidemiological studies indicate that MDPH-PA offers some protection to humans (4,5), recent reports (23,33) suggest that this vaccine may provide only partial protection against some strains of <i>B. anthracis</i>.” (emphasis added)</p>

¹¹ PRI, Inc. was to manufacture AVA at the National Cancer Institute at Ft. Detrick, MD under license from MDPH, and then ship the finished product to MDPH for bottling and storage. Although PRI, Inc was reportedly paid approximately \$15.4 million in a contract approved six months after the end of the 1991 Gulf War, DoD has asserted no vaccine was ever delivered under this contract.

¹² Ivins BE, Welkos SL, Little SF, Crumrine MH, Nelson GO. “Immunization against Anthrax with *Bacillus anthracis* Protective Antigen Combined with Adjuvants”, *Infection and Immunity*. (Feb 1992) 60(2);662-668. [Note: Dr. Ivins was an Army employee at Ft. Detrick, MD]

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Col (Dr.) Arthur Friedlander, M.D., memo to Deputy Commander, USAMRIID (Oct. 6, 1992)	Not cited	NO	"Although there are no data on MDPH-PA efficacy in humans , there is considerable information on its efficacy in guinea pigs, and rhesus monkeys." (emphasis added) (Statement in attachment to this memo was authored by Army Dr. Bruce Ivins) ¹³
Secretary of the Army Togo West, Jr., indemnification memo ¹⁴ (undated, 1993-1997)	Pl. Compl. para 41 (Mar. 18, 2003). Pl. Amend. Compl. Para 49. (Jan. 7, 2004)	NO	"...the unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the AVA. These concerns stem from: a) the limited use of the vaccine to date, i.e., tests prior to approval of the vaccine by the Food and Drug Administration are on too small a scale to permit accurate assessment of types and severity of adverse reactions (only widespread use can provide this assessment); and b) insufficient experience in mass immunization programs to truly evaluate the efficacy of the vaccine. Moreover, there is no way to predict whether the pathogen against which the vaccine may be used will be sufficiently similar to the pathogen used in tests to ensure vaccine efficacy." (Emphasis added).

¹³ Note: Dr. Ivins and Col (Dr.) Friedlander were co-authors of all three of the animal study articles (ref.. 2 thru 4) referenced in the FDA's Jan. 5, 2004 Final Rule. See:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/04-3135.htm>

¹⁴ Cited in House Report 106-556 (April 2000), p. 8-9. Memorandum of decision, undated, Secretary of the Army Togo West, Jr., authority under Public Law 85-804 to include an indemnification clause in contract DAMD17-91-C-1139 with the Michigan Biologic Products Institute [undated] (in House Government Reform Committee, National Security (Shays) subcommittee files). Mr. West was Secretary of the Army from Nov 22, 1993 - Dec 2, 1997.

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<p>Brachman and Friedlander, "Vaccines", 2nd Edition, p. 736 (ed. Plotkin and Mortimer) (1994)</p>	<p>Not cited</p>	<p>NO</p>	<p>"A controlled clinical trial was conducted with a vaccine similar to the currently licensed U.S. vaccine... the results indicated that vaccination, compared with inoculation with a placebo, provided 92.5% efficacy against cutaneous anthrax, with a lower 95% confidence limit of 65% effectiveness. No assessment of the effectiveness of the vaccine against inhalation anthrax could be made because there were too few cases."</p> <p>"...there have been no controlled clinical trials of the efficacy of the currently licensed U.S. vaccine. The vaccine has been extensively tested in animals..." (emphasis added)</p>
<p>Dr. Anna Johnson-Winegar¹⁵, Ph.D., Department of the Army, letter to MDPH, License Amendment Plan. (Oct. 5, 1995)</p>	<p>Pl. Compl. Para. 18-19 (Mar. 18, 2003). Pl. Amend. Compl. Para. 26-27. (Jan. 7, 2004)</p>	<p>NO</p>	<p>Dr. Johnson-Winegar: "I am enclosing a copy of a plan which addresses the types of studies needed to amend the approved immunization schedule for the anthrax vaccine and to expand the indication for use to include protection from aerosol exposure to B. anthracis spores."</p> <p>SAIC Corp. attachment: "This vaccine is not licensed for aerosol exposure expected in a biological warfare environment." (emphasis added)</p>

¹⁵ Dr. Johnson-Winegar, as a career DoD civil servant, was integrally involved in the Army's contract with MDPH, MBPI, and BioPort through direct involvement since before the 1991 Gulf War. In 2003, she ultimately retired from DoD as the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense. See: http://www.defenselink.mil/bios/winegar_bio.html

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Dr. Bruce Ivins, Col (Dr). Arthur Friedlander, et.al. ¹⁶ (1996)	Not cited	YES (AR 628-629)	“The data in this study demonstrates that the MDPH vaccine is highly efficacious against inhalation anthrax <u>in rhesus monkeys</u> . The rhesus monkey is a useful model for inhalation anthrax in humans, although <u>there is currently no know surrogate marker or in vitro correlate of immunity that allows for direct comparison of immunity in humans to that in monkeys.</u> ”
MBPI submission to FDA Center for Biologic Evaluation and Research director, Dr. Kathryn C. Zoon, IND Introductory Statement, 3.1. (Sep. 20, 1996)	Pl. Compl. Para. 22-25 (Mar. 18, 2003). Pl. Amend. Compl. Para . 30-33. (Jan. 7, 2004)	NO	“...The Department of Defense desires a vaccine capable of conferring a high level of specific protection against inhalation anthrax.” “A subsequent protocol will...also determine if any parameters of the immune response in humans can be correlated with protection against lethal aerosol spore challenge demonstrated in animals. The ultimate purpose of this IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule. ” (emphasis added)
FDA Lead Deputy Commissioner Friedman memo (Mar. 13, 1997)	Mem. Op., p. 24 (Dec. 22, 2003)	YES (AR 4031)	“...there is a paucity of data regarding the effectiveness of Anthrax Vaccine for prevention of inhalation anthrax...None of the 5 inhalation cases in this [Brachman] trial occurred in Anthrax Vaccine recipients, but <u>these data alone are insufficient to allow definitive statistical conclusions.</u> ”

¹⁶ Ivins BE, Fellows PF, Pitt MLM, Estep JE, Welkos SL, Worsham PL, Friedlander AM. Efficacy of a standard human anthrax vaccine against Bacillus anthracis aerosol spore challenge in rhesus monkeys. Salisbury Medical Bulletin, Special Supplement No. 87; 125-126 (1996) [Note: Dr. Ivins and Colonel Friedlander were both Army employees at Ft. Detrick, MD]

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<p>Dr. Anna Johnson-Winegar, Ph.D., Department of the Army¹⁷ (March 1997)</p>	<p>Not cited</p>	<p>NO</p>	<p>"...Field studies of efficacy cannot be performed, since exposure to most NBC agents does not usually occur naturally. Moreover, the high lethality and/or toxicity of NBC agents also makes it unethical to expose human subjects in controlled efficacy studies usually required by the FDA for product licensure...For these reasons, many NBC countermeasures are likely to remain in an Investigational New Drug (IND) status..." (page 3-4)</p> <p>"Presented research plan to the Joint Program Office for Biological Defense and the FDA in pre-IND meeting concerning a proposed amendment of the anthrax vaccine adsorbed license to reduce the number of required doses and to include an indication for aerosol exposure." (Page D-14)</p>
<p>Memo from Dr. Gerard Burrow, M.D. (Yale University), DoD's "independent expert on anthrax vaccine", to then-Undersecretary of Defense Rudy DeLeon (Feb 19, 1998)¹⁸</p>	<p>Not cited</p>	<p>NO</p>	<p>"...there have been no controlled clinical trials of the currently licensed US vaccine in humans. This vaccine has been extensively tested in animals and has protected non-human primates against an aerosol challenge..."</p>

¹⁷ Department Of Defense Nuclear/Biological/Chemical (Nbc) Defense, Annual Report To Congress, March 1997, Page 3-4 (pdf page 60) and Page D-14 (pdf page 199):
<http://www.acq.osd.mil/cp/nbc97.pdf>

¹⁸ Dr. Gerard Burrow is a former dean of Yale Medical School and was asked to be DoD's "independent expert" on anthrax vaccine in December 1997. After soliciting a report on anthrax vaccine safety and efficacy from Dr. Burrow, DoD has repeatedly cited his review as prove the vaccine is safe and

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Secretary of the Army Louis Caldera, indemnification memo (Sep. 3, 1998)	Pl. Compl. para 42 (Mar. 18, 2003). Pl. Amend. Compl. Para 50. (Jan. 6, 2004)	NO	“...The obligation assumed by MBPI under this contract involves unusually hazardous risks associated with the potential for adverse reactions in some recipients and the possibility that the desired immunological effect will not be obtained by all recipients. Although AVA has been extensively tested under the auspices of the Food and Drug Administration, the size of the proposed vaccination program may reveal unforewarned idiosyncratic adverse reactions. Moreover, there is no way to be certain that the pathogen used in tests measuring vaccine efficacy will be sufficiently similar to the pathogen that U.S. forces might encounter to confer immunity. ”
AVA FDA-approved Package Insert, p. 1. (Mar. 1999)	Pl. Compl., para. 59. (Mar. 18, 2003) Pl. Amend. Compl., Para 65. (Jan. 6, 2004)	NO	“Anthrax Vaccine Absorbed is used in man to promote increased resistance to <i>Bacillus Anthracis</i> by active immunization (1,2).”

effective. When asked to testify before the House Government Reform Committee in April 1999 about his review, Dr. Burrow declined. Dr. Burrow’s letter declining to appear is available on request).
http://www.defenselink.mil/other_info/burrows.html.

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Col (Dr.) Arthur Friedlander, et.al, <i>JAMA</i> . ¹⁹ (May 1999)	Not cited	NO	“ <u>A similar vaccine has been shown in 1 small placebo controlled human trial to be efficacious against cutaneous anthrax.</u> ”
Dr. Kenyon, DoD, Joint Vaccine Acquisition Program, AVIP conference official transcript. (May 25, 1999).	Schumm Decl., Atch. A, p. 34, 38. (Apr. 7, 2004)	NO	“There are vaccines that have been developed such as the VEE vaccine which protects very nicely against mosquito bites but does not protect very well against aerosol. So, we have to show the FDA that these vaccines protect against an aerosol challenge. <u>Aerosol, of course, is much more difficult to prove the efficacy than an aerosol against a parenteral challenge.</u> ”
Brachman and Friedlander, “ <i>Vaccines</i> ”, 3 rd Edition, p. 634-635 (ed. Plotkin and Mortimer) (1999)	Pl. Final Reply, p.13. (Apr. 25, 2003) Judge Emmett Sullivan, Mem. Op., p 24 (Dec. 22, 2003).	NO	“A controlled clinical trial was conducted with a vaccine similar to the currently licensed U.S. vaccine... the results indicated that vaccination, compared with inoculation with a placebo, provided <u>92.5% efficacy against cutaneous anthrax</u> (lower 95% confidence limit, 65%). <u>No assessment of the effectiveness of the vaccine against inhalation anthrax could be made</u> because there were too few cases.” “...there have been no controlled clinical trials of the efficacy of the currently licensed U.S. vaccine. The vaccine has been extensively tested in animals...”

¹⁹ Inglesby TV, Henderson DA, Bartlett JG, Ascher MS, Friedlander AM, Hauer J, McDade J, Osterholm MT, O’Toole T, Parker G, Perl TM, Russell PK, Tonat K, et al. Anthrax as a Biological Weapon. *Journal of the American Medical Association*. 281(18);1735-1745. (May 1999) [Note: Colonel (Dr.) Friedlander was an Army employee at Ft. Detrick, MD; MGen (Dr.) Phillip Russell (ret.) was a former commander at Ft. Detrick]

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IOM Report, p. 134-135. ²⁰ (1999)	Not cited	NO	"A licensed vaccine with demonstrated efficacy against cutaneous anthrax is available from Michigan Biological Products Institute... Franz et al. (1997) note that <u>there are few data regarding efficacy against inhalational anthrax in humans</u> , although the vaccine has been shown to provide protection in studies using rhesus monkeys..." (emphasis added)
Col (Dr.) Arthur Friedlander, et.al, <i>JAMA</i> . ²¹ (Dec 1999)	Not cited	NO	"Evidence for the efficacy of the licensed AVA is based on data from both humans and animal models. The only clinical study conducted in humans to evaluate efficacy used a less potent precursor in the development of the licensed AVA. <u>Efficacy was evaluated n a placebo-controlled, single blind study carried out in goat hair mill workers, in 4 New Hampshire mills from 1955 to 1959, at risk for cutaneous anthrax.</u> "

²⁰ Institute of Medicine, "Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response" (1999), Executive Summary and page 134-135.

(<http://books.nap.edu/books/0309061954/html/134.html#pagetop>)

(The IOM committee that issued this report included retired Major General Phillip K. Russell, USA, a former commander of the Army's biodefense research facility at Ft. Detrick, MD and Dr. Donald Henderson, who was named as HHS Secretary Tommy Thompson's bioterrorism advisor shortly after the 2001 anthrax letter attacks began. The "Franz" cited in the quote is retired Colonel David Franz, USA, also a former commander at Ft. Detrick.)

²¹ Friedlander AM, Pittman PR, Parker GW. "Anthrax Vaccine Evidence for Safety and Efficacy Against Inhalation Anthrax". *Journal of the American Medical Association*. 282(22):2104-2106. (Dec 1999) [Note: Colonel Friedlander and then-Lieutenant Colonel Pitman were both Army employees at Ft. Detrick, MD] [Note: Colonel Friedlander, in accurately noting the Brachman textile mills workers were "at risk for cutaneous anthrax", directly rebuts Defendants arguments that the Brachman study pertained to anthrax "generally" (Def. S.J. Reply, p. 6-7). In fact, Dr. Brachman noted in his published articles that there had not been a single case of inhalation anthrax at these mills from 1941-1957 – until his field trial began. Colonel Friedlander could not have been confused on this point, since he has frequently collaborated with Brachman in published articles.

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Dr. David A. Ashford, Centers for Disease Control ²² (Jul. 10, 2000)	Not cited	NO	“...for those of us working with the vaccine, we do not have specific information on the efficacy of the existing vaccine for the prevention of inhalation anthrax and we probably never will. ” (emphasis added)
IOM Report, p. 282-283. ²³ (2000)	Schumm Decl., p. 9. (Apr. 7, 2004)	NO	“Brachman and colleagues (1962) conducted the only randomized clinical trial of vaccination with a protective antigen anthrax vaccine. Although the vaccine used in the study was similar to the current vaccine...in that it was a PA vaccine, the manufacturing process has since changed and a different strain of anthrax bacillus is now used (GAO, 1999c)... ” “... The great majority of cases of anthrax were of the cutaneous type; <u>there were not enough cases of inhalation to determine if vaccination was effective against this, the most lethal form of anthrax.</u> ” (emphasis added)

²² Reuters Health, “Anthrax vaccine is safe, U.S. experts say”, Jul. 10, 2000. Dr. David A. Ashford, D.V.M. was quoted at a CDC-sponsored conference in July 2000. At that time he was one of two career CDC employees tasked to staff the CDC’s Advisory Committee for Immunization Practices (ACIP) recommendations for anthrax vaccine, which were published on Dec. 15, 2000 (quoted below). See: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4915a1.htm>

²³ Fulco, C. E., Liverman, C. T., & Sox, H. C. (Eds.), “Gulf War and Health: Depleted Uranium, Pyridostigmine Bromide, Sarin, Vaccines”. (Volume 1)(p. 282-283). Washington, D.C.: Institute of Medicine, National Academy Press. <http://books.nap.edu/books/030907178X/html/282.html>

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
Centers for Disease Control, ACIP. ²⁴ (Dec 2000)	Not cited	NO	“ The efficacy of AVA is based on several studies in animals, one controlled vaccine trial in humans (64), and immunogenicity data for both humans and lower mammalian species (47,49,57,65).” (emphasis added)
Dr. Bruce Ivins, Col (Dr). Arthur Friedlander, et.al., <i>Vaccine</i> . ²⁵ (Apr 2001)	FDA Final Rule, 69 Fed. Reg. 260, 266; Ref. 3. (Jan. 5, 2004)	YES (AR 621-627)	“Although there are no human clinical data on the efficacy of AVA , a 4-year placebo-controlled study from the 1950s demonstrated that a vaccine similar to AVA afforded a significant degree of protection in humans [3,4].” (emphasis added)
Col (Dr). Arthur Friedlander, et.al., <i>Microbiology</i> . ²⁶ (June 2001)	Not cited	NO	“ The licensed human Anthrax Vaccine Adsorbed (AVA) , prepared from culture supernatants of a toxigenic, unencapsulated strain of <i>Bacillus anthracis</i> , protects animals against inhalational anthrax. ” (emphasis added) [Note: This is the first sentence in this article.]

²⁴ Hughes JM, Cohen ML. Use of the Anthrax Vaccine in the United States. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention. *MMWR* 2000;49(No. RR-15) [Note: this CDC statement specifically rebuts Defendant arguments that the Brachman study, without animal studies, can serve as the basis for licensure of AVA. (See Def. Opp. S.J., Apr. 7, 2004, p. 18)]

²⁵ Fellow PF, Linscott MK, Ivins BE, Pitt MLM, Rossi CA, Gibbs PH, Friedlander AM. “Efficacy of a human anthrax vaccine in guinea pigs, rabbits, and rhesus macaques against challenge by *Bacillus anthracis* isolates of diverse geographical origin”. *Vaccine*.19;3241-3247 (Apr 2001) [Note: Dr. Ivins and Colonel Friedlander were both Army employees at Ft. Detrick, MD]

²⁶ Welkos S, Little S, Friedlander A, Fritz D, Fellows P. “The role of antibodies to *Bacillus anthracis* and anthrax toxin components in inhibiting the early stages of infection by anthrax spores”. *Microbiology*, 147(6);1677-1685. (June 2001)

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
<p>Dr. Bruce Ivins and Col (Dr.) Arthur Friedlander, et.al., <i>Fourth International Conference on Anthrax</i>.²⁷ (Jun 10-13, 2003)</p>	Not cited	NO	<p>“...it is important to determine whether there are isolates of the organism for which the vaccine is not efficacious... ...Vaccination of guinea pigs with AVA provided varying degrees of protection against challenge with virulent strains. Rabbits and rhesus macaques were well protected against anthrax spore challenge by AVA vaccination, whereas hamsters were afforded no protection by AVA. These data may reflect differences in either disease pathogenesis or intrinsic antibody response with respect to the animal model, and they emphasize the importance of examining multiple animal species in an attempt to model the effectiveness of human anthrax vaccine.”</p>
<p>Col (Dr). Arthur Friedlander, Dr. Bruce Ivins, et.al., <i>Current Topics</i>.²⁸ (Jan 2002)</p>	Not cited	NO	<p>“There are no human efficacy data for the current anthrax vaccine.” (emphasis added)</p>

²⁷ P. F. Fellows, M. K. Linscott, B. E. Ivins, M., M. Pitt, C. A. Rossi, S. F. Little, P. Gibbs, A. M. Friedlander, "Efficacy of the U.S. Human Anthrax Vaccine in Various Laboratory Animal Models", presentation, *Fourth International Conference on Anthrax*, p. 39 (June 2001) [Note: this presentation by leading Army researchers directly contradicts the IOM and FDA assertion that AVA is effective against all known strains. The Army researchers also make clear the tenuous science upon which using animal correlates of immunity to demonstrate human efficacy rests.] <http://www.asmusa.org/mtgsrc/AnthraxProgBook.pdf>

²⁸ Friedlander AM, Welkos SL, Ivins BE. Anthrax Vaccines. *Current Topics in Microbiology and Immunology*.271;20-32. (Jan 2002) [Note: Dr. Ivins and Colonel Friedlander were both Army employees at Ft. Detrick, MD]

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
<p>Dr. Lee Goldman, M.D., <i>The American Journal of Medicine</i>.²⁹ (Jan 2002)</p>	<p>Not cited</p>	<p>NO</p>	<p>“Also of note was that 300 workers at the plant had previously agreed to be randomized to a trial of anthrax vaccine. None of the 150 vaccinated individuals developed anthrax compared with four of the 150 controls (P<0.05). However, after controlling for the location of work within the processing plant, the authors* could not conclude that the vaccine truly had a protective effect.” [*i.e. Brachman, et. al.]</p>
<p>Dr. P.S. Brachman, M.D., <i>The American Journal of Medicine</i>.³⁰ (Jan 2002)</p>	<p>Not cited</p>	<p>NO</p>	<p>"In the 1957 epidemic, the employees worked in an environment in which there was significant contamination with Bacillus anthracis, as well as with other air borne pollutants, yet the incidence of inhalation anthrax was very low, and only occasional cases of cutaneous anthrax developed."</p>

²⁹ Goldman L., "Inhalation Anthrax Revisited", *The American Journal of Medicine*. 112(1);1-2. (Jan 2002) [Note: Dr. Goldman, the editor-in-chief of The American Journal of Medicine, was not an employee of Defendants DoD, FDA, or HHS. Dr. Goldman wrote this article to reintroduce the Brachman study to the scientific community after the post-9/11 anthrax letter attacks.]

³⁰ Dr. P.S. Brachman, "Inhalation Anthrax Revisited: A Note from the Original Authors", *The American Journal of Medicine*. 112(1);1-2. (Jan 2002) [Notably, Dr. Brachman, a career CDC employee who was at the time working on an anthrax vaccine study for the Institute of Medicine, did not take exception to Dr. Goldman's characterization of the Brachman study in the same issue of *The American Journal of Medicine*. Additionally, Dr. Brachman's comments refute assertions of the threat from anthrax made by Defendants' declarants Winkenwerder and Grabenstein.]

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
“BioThrax” (AVA) FDA-approved Package Insert, p. 2. (Jan. 2002)	FDA Final Rule, 69 Fed. Reg. 260, 266; Ref. 6. (Jan. 5, 2004)	YES (AR 638-644)	"A controlled field study using an earlier version of a protective antigen–based anthrax vaccine, developed in the 1950’s...In a comparison of anthrax cases between the placebo and vaccine groups, including only those who were completely vaccinated, the calculated vaccine efficacy level against all reported cases of anthrax combined was 92.5% (lower 95% CI = 65%)." ³¹
IOM Report, p. 5-6 (Mar. 6, 2002)	Schumm Decl., p. 9. (Apr. 7, 2004)	YES (AR 3303-3583)	“Evaluating Efficacy of AVA. The efficacy of a PA-containing anthrax vaccine similar to AVA against anthrax infection was established by a randomized controlled field study of textile mill workers (Brachman et al., 1962). Subsequent data from the Centers for Disease Control and Prevention (CDC) support the results of that study (FDA, 1985). The small number of inhalational cases in those studies provides insufficient information to establish the vaccine’s efficacy against inhalational infection , but the data <u>suggest</u> that the vaccine has a protective effect.” ³² (emphasis added)
IOM Report, p. 59. (Mar. 6, 2002)	Schumm Decl., p. 9. (Apr. 7, 2004)	YES (AR 3303-3583)	“... the small number of inhalational cases in those studies* <u>provides insufficient information to allow a conclusion about the vaccine’s efficacy against <u>inhalational infection</u> to be made.</u> ” ³³ (emphasis added) [*referring to both the Brachman and CDC Surveillance studies cited in the FDA Final Rule]

³¹ This most recent BioPort assertion of efficacy stands in stark contrast to the manufacturer’s preceding FDA-approved package insert, dated March 1999, as well as previous inserts in 1979 and 1987. Significantly, the 2002 package insert was developed after a lawsuit challenging the legality of the AVIP was filed in May 2001 (Case No. 1:01CV00941 TFH, D.C. Federal District Court).

³² IOM Report (2002), p. 5-6. See <http://books.nap.edu/books/0309083095/html/5.html#pagetop>

³³ IOM Report (2002), p. 59. See <http://books.nap.edu/books/0309083095/html/59.html#pagetop>

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
IOM Report, p. 76-77 (Mar. 6, 2002)	Schumm Decl., p. 9. (Apr. 7, 2004)	YES (AR 3303-3583)	<p>CONCLUSIONS REGARDING EFFICACY</p> <p>A vaccine similar to the licensed vaccine, AVA, was shown to be effective against <u>cutaneous</u> anthrax in humans in the field trial supporting the original application for licensure of AVA (Brachman et al., 1962). Although that study had too few cases to evaluate the vaccine's efficacy for the prevention of inhalational disease, the five inhalational cases observed occurred only among nonvaccinated or placebo recipients, whereas none occurred among vaccinated workers. Data from CDC on cases reported between 1962 and 1974 also indicated that the vaccine offered protection against the <u>cutaneous</u> form of the disease (FDA, 1985).³⁴ (emphasis added)</p>
Dr. Anna Johnson-Winegar, briefing. ³⁵ (Apr. 2, 2002)	Pl. S.J. Reply, p. 13 (footnote 13) (Apr. 21, 2004)	NO	"Brachman study suggests efficacy in humans against inhalational anthrax." (emphasis added)

³⁴ IOM Report (2002), p. 76-77. See <http://books.nap.edu/books/0309083095/html/76.html#pagetop>

³⁵ Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, briefing, to the Chemical and Biological Arms Control Institute, April. 2, 2002. (slide 11). See: www.acq.osd.mil/cp/winegarcbaic4-2-02.pdf

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

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Dr. C. Quinn ³⁶ , Centers for Disease Control FDA transcript, p. 142-143. ³⁷ (Apr. 23, 2002)	Pl. St. of Mat. Facts, para. 40, p. 11. (Mar. 3, 2004)	NO	"...In the context of AVA, its ability to prevent inhalational anthrax in humans is unknown. Although the Brachman study of the 1960s used inhalational anthrax cases as the denominator, the numbers were actually too small to come to a firm conclusion about inhalation protection." (emphasis added)
Col. (Dr.) Arthur Friedlander, USA, ret., M.D., FDA transcript, p. 212. ³⁸ (Apr. 23, 2002)	Pl. St. of Mat. Facts, para. 40, p. 11. (Mar. 3, 2004)	NO	"I think the overwhelming concern here is still--remains inhalational anthrax. Cutaneous anthrax is readily identified now--I mean, that's not to deny that it's a concern. But in regard to the other point, I think it's fair--there's not any data except in the guinea pig..." (emphasis added)
Dr. John Robbins ³⁹ , National Institutes of Health, FDA transcript, p. 215. ⁴⁰ (Apr. 23, 2002)	Pl. St. of Mat. Facts, para. 40, p. 11. (Mar. 3, 2004)	NO	"The best information is, in animals, that antibodies to PA alone will protect, and in humans, the information is limited. The only good clinical study we have shows that it protects against cutaneous anthrax 92 percent efficacy and it was 5 and 0 against inhalation. <u>Not enough for statistical significance</u>, but no breakthroughs." (emphasis added)

³⁶ Dr. Conrad Quinn, CDC Div. of Bacterial and Mycotic Diseases; member of the "Connecticut Anthrax Investigation Team"; Centers for Disease Control. See:

<http://www.cdc.gov/ncidod/EID/vol8no10/02-0399.htm>

³⁷ "Anthrax Vaccines: Efficacy Testing And Surrogate Markers Of Immunity Workshop, FDA Center for Biologics Evaluation and Research, transcript, April 23, 2002

<http://www.fda.gov/cber/minutes/anthrax0402.pdf>

³⁸ FDA transcript, Apr. 23, 2002, Id.

³⁹ Dr. John B. Robbins, M.D., Chief of the Laboratory of Developmental and Molecular Immunity, National Institutes of Child Health and Human Development at the National Institutes of Health.

⁴⁰ FDA transcript, Apr. 23, 2002, Id.

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
Journal of the American Medical Association ⁴¹ (May 2002)	NO	NO	<p>"Preexposure vaccination with AVA has been shown to be efficacious against experimental challenge in a number of animal studies. A similar vaccine was shown in a placebo-controlled human trial to be efficacious against cutaneous anthrax." (p. 2244) (emphasis added)</p> <p>"There are no controlled clinical studies for the treatment of inhalational anthrax in humans. " (p. 2245)</p>
Dr. Phillip S. Brachman <i>American Journal of Epidemiology</i> . ⁴² (June 2002)	Not cited	NO	<p>"Although five cases of inhalational anthrax occurred in one of the field trial mills (two in placebo recipients, and three among nonparticipants), the <u>results were not statistically significant</u> in view of the small number of events to address the efficacy of the vaccine in preventing inhalation anthrax." (emphasis added)</p>

⁴¹ Inglesby, O'Toole, **D. A. Henderson [Bioterrorism advisor to HHS Secretary Thompson]**, Bartlett, Ascher, Eitzen, **Arthur M. Friedlander [Col, USA, ret.; Army's top anthrax researcher]**, **Julie Gerberding [CDC Director]**, Hauer, Hughes, McDade, Osterholm, **Gerard Parker [Col, USA, ret.]**, Perl, **Phillip Russell [MGen, USA, ret.; former commander at Ft. Detrick]**, et.al.:

"Anthrax as a Biological Weapon, 2002: Updated Recommendations for Management", JAMA, May 2002; 287: 2236 - 2252. [emphasis added]

⁴² Brachman PS. Bioterrorism: An Update with a Focus on Anthrax. *American Journal of Epidemiology*.155(11);981-987 (June 2002)

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
<p>Department of the Army, USAMRIID, press release.⁴³ (Mar. 23, 2003)</p>	<p>Not cited</p>	<p>NO</p>	<p>“Each of the USAMRIID scientists contributed something unique. Pitt's expertise in aerobiology was tapped to design, conduct and interpret key aerosol studies of the vaccine's efficacy using animal models. She solved procedural problems related to the potency assay and helped plan the studies that compared different lots of anthrax vaccine in rabbits and among guinea pigs from different vendors, thus identifying a major source of variability in the potency assay. These studies paved the way to regaining AVA licensure, acting as an anchor that allowed test results obtained with numerous vaccine lots, conducted at different laboratories, to be compared in a meaningful way.” (emphasis added)</p>
<p>Dr. William Winkenwerder, Assistant Secretary of Defense for Health Affairs.⁴⁴ (Dec. 29, 2003)</p>	<p>Def. Motion to Dismiss, Winkenwerder Decl., para. 12. (Dec. 30, 2003)</p>	<p>NO</p>	<p>“The anthrax vaccine is safe and effective, and has been licensed by the Food and Drug Administration since 1970. The National Academy of Sciences states unequivocally that anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of Bacillus anthracis." In a series of controlled experiments among 65 monkeys exposed to inhalational anthrax and provided the vaccine, 62 survived. Among 18 exposed monkeys without the vaccine, all died.” (emphasis added)</p>

⁴³ Army press release, Mar. 23, 2003. [Note: The three Army researchers (Drs. Ivins, Pitt, and Little) mentioned in this Army press release are co-authors of one or more of the three animal studies cited as references 3, 4, 5 in FDA's Final Rule (69 Fed. Reg. 260, 266; Ref. 3-5). This Army press release makes clear that absent the animal rabbit and guinea pig potency tests developed by Army researchers, AVA's licensure could not have been “regained” – and implicit acknowledgement that the vaccine had been improperly licensed in 1970.

http://www.dcmilitary.com/army/standard/8_06/national_news/22098-1.html

⁴⁴ Dr. William Winkenwerder, letter to the editor, “Anthrax Vaccinations for U.S. Soldiers”, Los Angeles Times, Dec. 29, 2003.

Summary of Statements on Anthrax Vaccine (AVA) Efficacy

Citation	Doe v. Rumsfeld	FDA Admin Record	Statements ¹ on Anthrax Vaccine Efficacy
<p>FDA Final Rule, 69 Fed. Reg. 259 (Jan. 5, 2004)</p>	<p>Judge Emmett Sullivan, Order. (Jan. 7, 2004)</p>	<p>N/A</p>	<p>“FDA does not agree with the Panel report...FDA has determined that the calculated efficacy of the vaccine to prevent all types of anthrax disease combined was, in fact, 92.5 percent (lower 95 percent confidence interval = 65 percent). The efficacy analysis in the Brachman study includes all cases of anthrax disease regardless of the route of exposure or manifestation of disease. FDA agrees that the five cases of inhalation anthrax reported in the course of the Brachman study are too few to support an independent statistical analysis.”</p>