

# How “adequate and well-controlled” was the “clinical trial” of a human Anthrax vaccine, 1955-1959?

Walter R. Schumm, Ph.D. and Robert L. Brenneman, M.S.

School of Family Studies and Human Services

Justin Hall, Kansas State University

1700 Anderson Avenue

Manhattan, KS 66506-1403 USA

Phone: +1 785 539 3641 (home) +1 785 532 1494 (office)

Fax: +1 785 532 5505

Email: Schumm@humecc.ksu.edu (work) WRSchumm@aol.com (home)

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## Abstract

In late 2003, the Brachman et al. (1960, 1962) field study of an earlier anthrax vaccine became the basis for an FDA regulatory determination that the currently licensed vaccine is effective against *B. anthracis* strains, regardless of the route of exposure. Here, the Brachman et al. (1962) field study was reexamined in terms of the validity and completeness of its experimental design. Numerous limitations with respect to the trial's experimental design were either discovered or reaffirmed. Some of these limitations have never been explained satisfactorily for more than 40 years. In conclusion, our review indicates that Brachman et al.'s (1962) experimental design actually fell far short of being able to demonstrate, conclusively, the efficacy of the anthrax vaccine in humans, especially with respect to protection against inhalation anthrax. Any claim that the early trial of the vaccine was truly “adequate and well-controlled” must depend upon a consideration of only very limited information about the numerous weaknesses of that trial's experimental design.

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