

The FDA's acceptance of Brachman's 1950's anthrax research: Good politics? Maybe. Good science? No.

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Abstract

In December 2005, the U.S. Food and Drug Administration (FDA) released its Final Order on anthrax vaccine, declaring it to be 92.5% effective for preventing both inhalation and cutaneous anthrax infections. While the FDA failed to discuss in its report many of the limitations found in the original research reports by Brachman *et al.* (1960, 1962), it did rebut an argument presented previously in *Medical Veritas* (2005) concerning the lack of statistical justification for combining data from the four textile mills involved in Brachman's studies. In contrast to the FDA's conclusions, research here demonstrates that the vaccine's efficacy was not consistent across the four mills, varying substantially from one mill to the next and was lower, across all the four mills, than the alleged 92.5% rate. It is observed that the Arms Mill, which had only nine cases of anthrax during its "epidemic," had over 200 cases of the flu during the same time period. Even the number of subjects in the treatment and control groups changed from one report (1960) to another (1962). Not only was Box's M test significant, indicating that data from the four mills should not be combined, Levene tests indicated similar problems with heterogeneity of variance across data from the four mills. A variety of statistical tests support the hypothesis that there were substantial differences among the four mills, especially in terms of refusal rates, which had a direct bearing on the validity of the way in which subjects were divided between treatment and control groups. FDA's regulatory decisions with respect to anthrax vaccine absorbed, while politically expedient, appear to lack the scientific basis mandated in federal statute and affirmed by U.S. Supreme Court precedents.

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Keywords: Anthrax vaccine, limitations of research, scientific ethics, vaccine efficacy, inhalation anthrax
