



DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258



REPLY TO
ATTENTION OF

AFEB (15-1a) 98-2

09 January 1998

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendation for Japanese Encephalitis Vaccine

1. In a 14 March 1996 memorandum, the Armed Forces Epidemiological Board (AFEB), in response to a request to consider whether it was reasonable to increase the interval between the Japanese encephalitis (JE) vaccine primary series and booster dose from two to three years made the following recommendations:
 - a. Changing to a three-year schedule.
 - b. Obtaining more data on JE antibody level decline at three years.
 - c. That the results of the above study be reported back to the AFEB.

2. At its 11 December 1997 meeting, the Board was briefed on the results of a retrospective cohort serosurvey of 68 active-duty Marines who had received a three-dose primary series of JE vaccine between 1 and >4 years previously, and had antibody titers performed. The results of this study as presented are confusing, but fit best with an interpretation that either recent lots of JE vaccine are significantly less immunogenic than older lots of vaccine, or that in recent years JE vaccine is being improperly handled/stored/administered. In addition, the Board heard anecdotal evidence that the latter concern was justified.


3. Based on this information, the Board makes the following recommendations:
 - a. **THE NAVY BE TASKED WITH CONDUCTING A HIGH QUALITY, COMPREHENSIVE, RETROSPECTIVE COHORT SEROSURVEY WITH ADEQUATE POWER AND APPROPRIATE STUDY DESIGN TO DETERMINE WHETHER A SIGNIFICANT DECLINE IN JE ANTIBODY TITERS TO NON-PROTECTIVE LEVELS OCCURS AT THREE YEARS COMPARED TO TWO YEARS AFTER THE PRIMARY SERIES, ACROSS AGE AND GENDER CATEGORIES.**

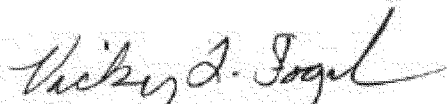
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- b. EFFECTIVE IMMEDIATELY, THAT A MEMORANDUM BE ISSUED TO ALL DOD SITES THAT ADMINISTER JE, VACCINE REVIEWING:
- 1) PROPER STORAGE AND HANDLING OF JE VACCINE.
 - 2) PROPER ADMINISTRATION AND DOSING OF JE VACCINE, WITH PARTICULAR EMPHASIS ON THE FACT THAT THE VACCINE IS TO BE ADMINISTERED SUBCUTANEOUSLY.
- c. THAT THE FDA AND MANUFACTURER BE NOTIFIED OF THE PRESENT SEROSURVEY RESULTS AND FORMALLY QUERIED ABOUT POSSIBLE PROBLEMS WITH LOT TO LOT VARIABILITY, CHANGES IN IMMUNOGENICITY, POTENCY AND STABILITY OVER THE LAST FOUR YEARS, AND/OR CHANGES IN VACCINE SHELF LIFE OVER THIS TIME PERIOD.
- d. THE RESULTS OF THE ABOVE PROPOSED SEROLOGIC STUDIES SHOULD BE REPORTED BACK TO THE AFEB WITHIN 12 MONTHS.

4. The above recommendation was proposed and discussed by the Infectious Disease Subcommittee on 11-12 December 1997, and endorsed by the full Board on 12 December 1997.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:


GERALD F. FLETCHER, M.D.
AFEB President


VICKY L. FOGELMAN
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AFEB Executive Secretary

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