DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

AFEB (15-1a) 90-4

27 February 1990

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: Recommendations on Varicella Vaccine Trial in Navy Recruits

1. During its meeting of 22 February 1990 the Armed Forces Epidemiological Board (AFEB) met to consider a request from The Surgeon General, U.S. Navy concerning a proposed varicella virus vaccine field trial in Navy recruits. The request memorandum is provided at enclosure 1.

2. During the meeting, presentations by Navy and Army epidemiologists described the experiences of the military services concerning the clinical disease of this infection. A representative of Mercke Sharpe and Dohme provided pertinent data and other valuable information as the manufacturer of the candidate vaccine.

3. The Board is concerned over the increasing incidence of varicella in the services, especially in training centers, the deaths of two servicemen from complications of the disease and interference with unit missions caused by related epidemics. It was noted that the vaccine had been predominantly used on leukemic children who were in remission of their malignant disease, and that its use was free of adverse reactions; herpes zoster occurred after vaccinations less frequently than among unimmunized leukemic children infected with wild virus. In healthy children, the vaccine elicited specific antibodies in 96% of those evaluated and had an efficacy in preventing disease approaching 100% while 4-7% of the recipients developed a rash 2-3 weeks after vaccination, no clinical symptoms were noted among their contacts. Experience with adult recipients has not been as extensive with only 88% developing antibodies suggesting that a larger dose or second injection of this attenuated virus may be necessary. Those cases which did occur among those vaccinated were very mild. One healthy vaccinated adult developed mild herpes zoster three years after vaccination; however, the virus isolated from the lesions proved not to be vaccine derived, but a wild strain.

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SUBJECT: Recommendations on Varicella Vaccine Trial in Navy Recruits

4. In view of these facts, the Board recommends that:

a. **VARIVAX, THE PROPOSED VACCINE, APPEARS TO DEMONSTRATE SUFFICIENT SAFETY, PROBABLE IMMUNOGENICITY AND POTENTIAL EFFICACY TO PERMIT A VACCINE TRIAL IN NAVY RECRUITS.**

b. **THERE IS ADEQUATE EVIDENCE THAT VARICELLA IS A SIGNIFICANT PROBLEM AMONG NAVY PERSONNEL, ESPECIALLY THOSE UNDERGOING TRAINING.**

c. **BASED ON THESE FACTORS, THE BOARD CONCURS THAT THE STUDY BE PERFORMED.**

d. **IT IS TOO LATE TO INITIATE TRIALS IN THE 1989-1990 SEASON. IT WOULD BE BEST TO INITIATE THE IMMUNIZATION PROGRAM 6-8 WEEKS BEFORE THE EXPECTED BEGINNING OF THE DISEASE OUTBREAK BASED ON THE EXPERIENCE OF PREVIOUS YEARS.**

e. **THE FOLLOWUP PERIOD FOR ANTIBODY STUDIES SHOULD BE ONE YEAR; CLINICAL FOLLOWUP THROUGH ALERTED DISEASE REPORTING FUNCTIONS SHOULD BE AS LONG AS POSSIBLE.**

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Theodore E. Woodward

Robert A. Wells

Encl

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

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AFEB (15-1a) 90-4 28 March 1990

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THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

Subject: Correction of Armed Forces Epidemiological Board Recommendation 90-4 dated 27 February 1990

1. Recently an error was detected on the first page of the above AFEB recommendation which concerns the proposed varicella vaccine trial in Navy recuits. Specifically, line 6 of paragraph 3 currently contains the phrase..."and that its use was full of adverse reactions." This should read ..."and that its use was free of adverse reactions."

2. Please find enclosed a corrected copy.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

Encl

THEODORE E. WOODWARD, M.D.
President, AFEB

ROBERT A. WELLS, Ph.D.
Colonel, USA, MSC
Executive Secretary

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DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
WASHINGTON, D.C. 20372-5120

IN REPLY REFER TO

6230:5420/1
Ser 24/0455
21 Dec 89

MEMORANDUM FOR THE EXECUTIVE SECRETARY, ARMED FORCES EPIDEMIOLOGICAL BOARD

Subj: VARICELLA VIRUS VACCINE TRIAL IN NAVY RECRUITS - ACTION MEMORANDUM

Encl: (1) Proposed varicella virus vaccine trial protocol
(2) Data from Merck Sharp and Dohme w/scientific literature

1. In 1988 there were over 1500 cases of varicella in active duty Navy personnel, at an estimated cost of over $2 million for hospital admissions. Two active duty members died of severe varicella and its complications. Additionally, a Navy ship had to abort its mission when 11 percent of the crew of 994 developed varicella. The largest proportion of cases were seen at Naval Training Center, Great Lakes, Illinois which had 614 cases in 1988 and 520 cases so far in 1989.

2. The Commander, Naval Education and Training Command requested Naval Medical Department assistance. After due consideration, it was determined that the only practical intervention would be a vaccine trial using the Merck Sharp and Dohme (MSD) investigational vaccine, Varivax. Because the usual Varivax formulation, approximately 1000 pfu per dose, is less immunogenic in adolescents and young adults than in children, a regimen using higher doses and/or multiple doses appeared to be necessary.

3. We request that the Board convene a special session to review the issues of concern, and to advise us in time to begin the project in January 1990. We seek advice on four questions.

a. Does Varivax appear to demonstrate sufficient evidence of safety, probable immunogenicity, and potential efficacy to permit a vaccine trial in Navy recruits?

b. Is there sufficient evidence of a significant varicella problem among Navy personnel, especially recruits, to justify a vaccine trial in Navy personnel?

c. Should an attempt be made to initiate the trial this winter, 1989-90?

d. How long should the follow-up period last?

4. Enclosure (1) is the proposed vaccine trial protocol and enclosure (2) is data from MSD with pertinent scientific literature.

Subj: VARICELLA VIRUS VACCINE TRIAL IN NAVY RECRUITS - ACTION MEMORANDUM

5. My point of contact on this subject is Captain W. F. Bina III, MC, USN, Director, Occupational Health and Preventive Medicine Division, at 653-1788.

W. A. BUCKENDORF
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