DEFENSE HEALTH BOARD
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DHB

JUN 04 2009

MEMORANDUM FOR: ELLEN P. EMBREY, DEPUTY ASSISTANT SECRETARY OF DEFENSE (FHP&R), PERFORMING THE DUTIES OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

SUBJECT: Vaccine Safety and Effectiveness Work Group Findings from Preparatory Meeting

1. References:

a. Presentation: Studies of the Safety and Immunogenicity of Vaccines of Military Significance: Past, Present, and Future, to the Vaccine Safety and Effectiveness Workgroup of the Defense Health Board, 2 June 2008, by COL Philip Pittman, Director, Vaccine Clinical Research Center U.S. Army Medical Research Institute of Infectious Diseases.

b. Presentation: Anthrax and Smallpox Vaccinations: Reliability and Measures of Health, to the Vaccine Safety and Effectiveness Workgroup of the Defense Health Board, 2 June 2008, by Tyler Smith, PhD, Director, Department of Defense Center for Deployment Health Research Naval Health Research Center.

c. Presentation: Armed Forces Health Surveillance Center: Vaccine Safety and Efficacy Studies, to the Vaccine Safety and Effectiveness Workgroup of the Defense Health Board, 2 June 2008, by Angelia Eick, PhD, ScM, Armed Forces Health Surveillance Center.

d. Presentation: ACAM2000: FDA Mandated Post-Marketing Requirements, to the Vaccine Safety and Effectiveness Workgroup of the Defense Health Board, 2 June 2008, by LTC Patrick Garman, Military Vaccine Agency.

e. Presentation: Vaccine Safety, Effectiveness, and Surveillance of the Department of Respiratory Disease Research, Naval Health Research Center to the Vaccine Safety and Effectiveness Workgroup of the Defense Health Board, 2 June 2008, by CDR Kevin Russell, Director, Department of Respiratory Disease Research, Naval Health Research Center.

f. Presentation: Vaccine Safety and Efficacy: Supporting the Military Health System (MHS) Immunization Programs, to the Vaccine Safety and Effectiveness Workgroup of the Defense Health Board, 2 June 2008, by COL Renata Engler, Director, Vaccine Healthcare Centers (VHC) Network.

g. Presentation: Vaccines in the Military Armed Forces Epidemiological Board (AFEB) Report 1999, to the Vaccine Safety and Effectiveness Workgroup of the Defense Health Board, 2 June 2008, by Dr. Gregory A. Poland, DHB President.

h. Presentation: Immunizations and Reproductive Health: Update on Recent Studies of Anthrax and Smallpox Vaccines in the U.S. Military, to the Vaccine Safety and Effectiveness Workgroup of the Defense Health Board, 2 June 2008, by Dr. Margaret Ryan, Director, Department of Defense (DoD) Center for Deployment Health Research.

2. At the request of Ms. Embrey, Deputy Assistant Secretary of Defense, Force Health Protection and Readiness, the Defense Health Board was asked to form a Vaccine Safety and Effectiveness Work Group composed of Defense Health Board (DHB) members, to examine the following:

a. Department of Defense (DoD) post-licensure vaccine safety, effectiveness, and surveillance studies.

b. Available published and unpublished data from DoD researchers evaluating the safety and effectiveness of vaccines currently in use by the DoD.

c. Future vaccine safety, effectiveness, and surveillance studies in the DoD.

3. The Workgroup received briefs during their preparatory meeting on 2 June 2008 from the Military Vaccine Agency (MILVAX), U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the DoD Center for Deployment Health Research Naval Health Research Center (NHRC), and the Vaccine Healthcare Centers (VHC) Network.

FINDINGS

4. Anthrax Vaccine Adsorbed (AVA) has been the focus of a preponderance of recent research pertaining to the safety and efficacy of vaccines. However, a transition is pending to a next generation of vaccines.

5. Evidence to date suggests AVA has few, if any, long-term clinical significant adverse events; however, further research, which is currently underway through the Centers for Disease Control and Prevention (CDC), can ascertain whether a positive association exists in regard to specific clinical outcomes.

6. Current research findings suggest a lack of positive association between anthrax vaccination and hospitalization due to the following specific outcomes: autoimmune diseases, asthma, amyotrophic lateral sclerosis (ALS), systemic lupus erythematosus (SLE), or fibromyalgia; however, service members who received the smallpox vaccine in 2003 and 2004 experience a slightly higher risk of hospitalization post-vaccination, especially due to asthma, autoimmune diseases, and myopericarditis. These findings require further research and confirmation.

7. Significant progress has been made with regard to adenovirus vaccine research, but timelines for deploying the vaccine continue to slip and lead to continuing delays.

8. Immunogenetic research is critical to understanding variations in immune responses, and in informing new vaccine development, but the necessary expertise and architecture within the DoD to carry out these studies is lacking.

9. Current DoD approaches to vaccine safety research do not include cross-disciplinary efforts.

10. Although involvement of the National Guard and Reserve components has significantly increased over the last decade in the planning and implementation of immunization programs, a paucity of studies regarding vaccine safety and efficacy in these populations is apparent.

11. Currently, no established post-marketing entity for pharmaceutical research exists within the DoD. The Board sees this as a potentially valuable area whereby opportunities, advancements, and inherent risks for matters pertaining to pharmaceutical research within the DoD may be confronted.

CONCLUSIONS

12. The Board endorses the organizational structure regarding MILVAX as the executive agent and command for the Vaccine Healthcare Network, and the continuation of MILVAX as the focal point for execution of vaccine policy, safety, effectiveness, particularly with respect to intergovernmental coordination of Phase IV vaccine studies.

13. The Board would like to complement MILVAX for their long-standing efforts in coordinating U.S. military immunization programs worldwide, assisting leaders in policy development, promoting quality in immunization delivery, and enhancing the scientific understanding of vaccines.

14. The Board believes that MILVAX could play an additional enhanced role in clinical vaccine studies, particularly with respect to post-licensure safety studies.

RECOMMENDATIONS

15. Based on these findings, the Board provides the following recommendations to the Department:

a. Specific, well-defined criteria should be established that would appropriately define the portfolio of AVA research based on the pending transition to the next generation of anthrax vaccines, and the soon-to-be-published results of the multicenter long-term AVA study conducted by the CDC.

b. Research infrastructure within the DoD should be established for carrying out immunogenetic vaccine response research. Due to the substantial costs associated with this research, high visibility issues should be selected for investigation, while opportunities for collaboration with outside investigators, including additional formal ways to work in partnership with academia, should be developed and enhanced.

c. Interdisciplinary approaches to vaccine safety and efficacy studies should be pursued and implemented. MILVAX may have particular opportunities in this regard.

d. Where possible, vaccine safety and efficacy research should include both the National Guard and Reserve components in their study populations.

e. The Department should build upon pre-existing infrastructure to establish a central office within the DoD that would address and manage all Phase IV post-marketing Departmentally-driven pharmaceutical research.

f. Pharmaceutical research conducted within the DoD needs to achieve greater visibility outside the Department. Coordination with other Federal agencies, participation in an external validation process, and an appropriate prioritization of research, would facilitate this process.

16. The above recommendations were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:

Gail Wilensky, PhD
DHB President

Gregory A. Poland, M.D.
Chair, Vaccine Safety and Effectiveness Workgroup

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