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Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

TO: INTERESTED PARTIES

SUBJECT: EXEMPTION TO HEALTH AND SAFETY CODE SECTION 124172
(MERCURY-CONTAINING VACCINES) FOR JAPANESE
ENCEPHALITIS VIRUS VACCINE INACTIVATED, 2009-10

In 2004, in order to ensure that pregnant women and children under age three years have access to mercury-free vaccines, Governor Schwarzenegger signed Assembly Bill (AB) 2943 (Pavley, Chapter 837, Statutes of 2004). Effective July 1, 2006, under the terms of Assembly Bill (AB) 2943, vaccines containing levels of mercury greater than specified limits cannot be administered to pregnant women and young children, except under certain circumstances.

While commonly used vaccines administered in the United States are available in mercury-free formulations for children and adolescents, the less frequently used Japanese Encephalitis vaccine is not. Japanese Encephalitis, a mosquito-borne infection, is the leading cause of viral encephalitis (brain infection) in Asia and parts of Oceania. Since 2005, major outbreaks of Japanese Encephalitis have resulted in illness and death of thousands of persons in India and Nepal. Most persons with encephalitis caused by the Japanese Encephalitis virus either die or have residual neurologic disease. Unimmunized children in affected areas are at highest risk of Japanese Encephalitis, while infection during pregnancy may cause miscarriage. There is currently no treatment for Japanese Encephalitis. Each year, approximately 4,300 Californians (excluding military) one year of age and older traveling for a month or longer in Asia or Oceania receive the Japanese Encephalitis vaccine in accordance with national medical and public health recommendations.

Prior to March 2009, the U.S. Food and Drug Administration (FDA) had licensed only one vaccine against Japanese Encephalitis for use in the United States. The formal name of the vaccine is Japanese Encephalitis Virus Vaccine Inactivated, and its trade name is JE-VAX®. It is manufactured by The Research Foundation for Microbial Diseases of Osaka University (“BIKEN®”) and distributed in the United States by

Sanofi Pasteur, Inc.

In March 2009, FDA licensed the use of a second Japanese Encephalitis vaccine which is free of preservatives, including those containing mercury, for use in persons 18 years of age and older. This vaccine may be given to pregnant adults now and someday may also be licensed for use in children and adolescents.

Given the continuing absence of mercury-free Japanese Encephalitis vaccine for persons younger than 18 years of age and the risk of fatal disease or brain injury from Japanese Encephalitis, Health and Human Services Agency Secretary Kimberly Belshé has exercised the authority provided by AB 2943, with concurrence from Governor Schwarzenegger, and granted an exemption from California Health and Safety Code Section 124172 (a) for Japanese Encephalitis Virus Vaccine Inactivated in persons under 18 years of age for another year from July 1, 2009 to June 30, 2010. Previous 12-month exemptions for Japanese Encephalitis vaccine have been granted since July 2006 under the same authority for the same reasons. This exemption will allow the Japanese Encephalitis vaccine to be administered to children younger than three years old and pregnant women younger than 18 years of age to protect against severe illness or death should they visit affected areas for extended periods of time.

Secretary Belshé and Governor Schwarzenegger have granted this exemption because of the health risk posed by Japanese Encephalitis virus to those residing or traveling in affected areas, and because there is no alternative vaccine for Californians seeking protection against Japanese Encephalitis.

Governor Schwarzenegger and Secretary Belshé remain deeply committed to implementing AB 2943 and ensuring that pregnant women younger than 18 years of age and young children have access to mercury-free vaccines whenever possible.

If you have any questions, please contact the California Department of Public Health Immunization Branch at (510) 620-3737.

Sincerely,



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Director