

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



SANDRA SHEWRY
Director



ARNOLD SCHWARZENEGGER
Governor

July 7, 2006

TO: INTERESTED PARTIES

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

In 2004, in order to ensure that pregnant women and children under age 3 have access to mercury-free vaccines, Governor Schwarzenegger signed AB 2943 (Pavley, Chapter 837, Statutes of 2004). Effective July 1, 2006, AB 2943 provides that vaccines containing specific levels of mercury cannot be administered to pregnant women and young children, except under certain circumstances.

While the commonly used influenza vaccine administered in the United States has an available mercury-free alternative, the more rare Japanese Encephalitis (JE) vaccine does not. The JE vaccine is only used for individuals traveling for a month or longer in certain areas of Asia and parts of Oceania. JE, a mosquito-borne infection, is the leading cause of viral encephalitis in Asia and parts of Oceania. Unimmunized children in affected areas are at highest risk of infection. Most persons with encephalitis caused by the JE virus either die or have residual neurologic disease. Infection during pregnancy may cause miscarriage. There is currently no treatment for JE. Each year, approximately 4,300 Californians (excluding military) over the age of 1 receive the JE vaccine in accordance with medical and public health recommendations.

The federal Food and Drug Administration (FDA) has licensed only one vaccine against JE 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 in Japan by The Research Foundation for Microbial Diseases of Osaka University ("BIKEN®") and distributed in the United States by sanofi pasteur, Inc.

Given the absence of mercury-free JE vaccine and the risk of fatal disease or brain injury from JE, Health and Human Services Agency Secretary Kimberly Belshé 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 from July 1, 2006 to June 30, 2007. This exemption will allow the JE vaccine to be administered to children younger than three years old and pregnant women to protect against severe illness or death should they visit affected areas for extended periods of time.

Secretary Belshé and Governor Schwarzenegger 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 and young children have access to mercury-free vaccines. Based on what we know at this time, we anticipate that there should be adequate mercury-free flu vaccine for children and pregnant women for the 2006 flu season. The Governor is contacting manufacturers of mercury-free vaccines to underscore the importance of maximum production of the vaccines.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Mark B. Horton', with a long horizontal flourish extending to the right.

Mark B. Horton, MD, MSPH
State Public Health Officer