



American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN™

California District IX



KAISER PERMANENTE®

October 25, 2006

Secretary Kim Belshe
State Capitol Building
Sacramento, California 95814

RE: Request for Exemption

Dear Secretary Belshe:

Children under three in California are being denied access to influenza vaccination because of inadequate supplies of thimerosal-free vaccine. California Safety Code Section 12472 (Chapter 837, Statutes of 2004, AB2943, Pavley) prohibits the use of thimerosal-containing vaccines in children less than 3-years of age, unless an exemption is declared. The American Academy of Pediatrics, California (AAP-CA), the California Medical Association (CMA), Kaiser Permanente, and the California Academy of Family Physicians (CAFP) respectfully request that the Administration grant a time-limited exemption during the anticipated period of supply shortage of thimerosal-free influenza vaccine. This is in the interest of preventing influenza-caused morbidity and mortality in California's youngest children, and protecting the public health of all Californians through stemming the spread of influenza from children to the elderly and others.

The circumstances creating the need for an exemption are as follows:

1. Novartis, which was to provide the California Department of Health Services clinics with thimerosal-free vaccine, decided not to provide this formulation of vaccine this year.
2. Sanofi-Pasteur, the only source of thimerosal-free vaccine, experienced poor growth of one of the viral strains to be included in the vaccine, which delayed adequate production. It is unlikely that sufficient quantities will be received in time for the beginning of the influenza season. We are already one month behind in starting influenza vaccinations for infants and young children requiring thimerosal-free vaccine in California.
3. The American Academy of Pediatrics, Committee on Infectious Diseases decided two weeks ago that children who received their first dose of vaccine last year should receive two doses of vaccine this year because of two new virus types in 2006-2007 vaccine. This doubles the amount of vaccine necessary for many children; a circumstance not anticipated by pediatricians when ordering vaccines earlier this year.

Under these circumstances, we believe an exemption should be declared for the following reasons:

1. The lack of adequate supply is creating a situation that is dangerous. Infants and young children who acquire influenza have hospitalization rates as high as those of adults at high-risk for influenza.

2. Survey responses from over 200 pediatricians tell us that the majority have not received their full allotment of thimerosal-free vaccine, and as a result have had to turn away patients without vaccinating. Over 70% say that they do have thimerosal-containing vaccine that they could shift to children under three if an exemption were granted. Eighty-five percent of respondents support an exemption for the use of thimerosal-containing vaccine.
3. While some families may be able to obtain thimerosal-free vaccine later in the season, those who face transportation and other barriers may not be able to return to their children's provider for vaccination. For these children, a delayed vaccination is vaccination foregone for the season.

California is the only state in the 2006-2007 influenza season to limit the use of thimerosal-containing influenza vaccine. Only six other states have laws restricting such vaccines, but they do not apply for this year. Illinois received waivers on public health grounds to allow use of nearly all vaccines, including influenza vaccine, which exceed its thimerosal limit. The laws in Iowa and Delaware exempt influenza vaccine from thimerosal limits. The laws in Washington, New York and Missouri go into effect in 2007 or 2008.

The Legislature and the Governor provided for an exemption in the current law so that parents of young children can have options to vaccinate them with other formulations against the flu, if desired. Given the very serious and real risk of flu for young children, and the inadequacy of current supply of vaccine that does meet the law's restrictions, we urge you to exercise that exemption.

If you have any questions, please do not hesitate to contact us. We stand ready, should such an exemption be granted, to do work with the appropriate state entities on outreach, and to disseminate the information promptly through our physician networks to support full immunization of California's children in a timely manner this season against the flu.

Sincerely,


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