



Rod R. Blagojevich, Governor
Eric E. Whitaker, M.D., M.P.H., Director

525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.idph.state.il.us

December 28, 2005

Dear Colleague:

As you are aware, Public Act 94-0614, Mercury-Free Vaccine Act, becomes effective on January 1, 2006. This Act requires vaccines to be mercury-free except for trace amounts, but provides in the statute a means for the Department to evaluate and assess the needs of Illinois citizens to have access to vaccines. The Illinois Department of Public Health will file a statewide Declaration of Exemption on behalf of public and private health care providers for the following vaccines affected by the Act: Influenza, Japanese Encephalitis, combined Tetanus-Diphtheria, and Meningococcal vaccines.

- **Influenza Vaccine**

Ninety percent of the influenza vaccine distributed each year is purchased by private clinicians. To date, more than 1,732,270 doses of influenza vaccine have been distributed in Illinois. Of these doses, almost 1.3 million doses have been distributed in by private sector providers through: outpatient clinics; HMOs; surgical centers; hospitals; renal dialysis units; long-term care facilities; corporations; resellers; pharmacies; and other private entities. The remaining doses were distributed to state and local health departments (locals via purchasing consortiums or individual public contracts), correctional facilities and other governmental entities.

It's important to know that in Illinois, local health departments and private providers have provided immunization services to adults or other high risk individuals since the mid-1970's. Vaccine is purchased by the individual provider or local health department with local funds. In addition, Public Act 93-0384 requires vaccination of residents in long-term care facilities annually with influenza and pneumococcal vaccines. This high risk population is routinely recommended as a priority for receiving vaccine according to the U.S. Advisory Committee on Immunization Practices (ACIP).

Current manufacturing practices limit the total amount of preservative-free product that is available to either the private or public sector providers throughout the U.S. The primary flu vaccine supplier, sanofi pasteur has distributed more than fifty eight million doses of Fluzone®, influenza virus vaccine, in the U.S. An estimated eight million doses are free of preservative (containing no thimerosal). Of the eight million doses, approximately six million is in the pediatric dosage (.25ml) and approximately two million doses

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are in the .5ml presentation. Next year, sanofi plans to produce approximately the same amount of the No Preservative Fluzone® vaccine as produced this season. The manufacturer does not reserve unpreserved influenza vaccine doses for any state, and it can not target the vaccine for any one state. Therefore, the Illinois Department of Public Health has determined that insufficient amounts of preservative-free Influenza vaccine are available to protect the health of Illinois residents, and will issue an exemption for the influenza vaccine.

- **Japanese Encephalitis Vaccine**

Japanese Encephalitis Vaccine (JEV) contains thimerosal in quantities greater than trace amounts. This vaccine is used in persons who plan to reside in or travel to areas where Japanese Encephalitis is endemic or epidemic during a transmission season. Because this vaccine is targeted to a specific at-risk population, the manufacturer has no plans to change the vaccine to a thimerosal-free formulation. Therefore, travelers in Illinois who require this vaccine will not be able to access this vaccine through their health care providers and will not be protected according to travel recommendations. Thus, the Illinois Department of Public Health has determined that JEV should be included in the Declaration of Exemption from P.A. 94-0614.

- **Combined Tetanus-Diphtheria Vaccines**

Although the Td vaccine, DECAVAC(tm) Tetanus and Diphtheria Toxoids Adsorbed, as manufactured by sanofi, is available in a preservative-free, single-dose, pre-filled syringe containing only trace amounts of thimerosal from the manufacturing process, other distributors offer a product that exceeds the thimerosal content mandated by this Act. This product is less expensive than the competing product and has been more readily available than the sanofi formulation. Therefore, due to the immunization requirements for booster doses in secondary and post-secondary education, the Department has determined that this vaccine shall be declared exempt from the mandates of the Mercury-Free Vaccine Act.

- **Meningococcal Vaccine**

Multi-dose Meningococcal vaccine (MPV) is currently produced in a single dose and multi-dose presentation. The multi-dose presentation exceeds 1.25 micrograms of preservative. In the event of an outbreak of meningococcal disease (i.e., in a university setting), it is critical to provide protection for at-risk individuals without delay. Delays in procuring a preservative-free formulation may result in illness and death among exposed individuals, when multi-dose MPV is readily available. Therefore, the Illinois Department of

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Public Health has determined that the multi-dose presentation of MPV must be included in the exemption of the Act.

The Illinois Department of Public Health supports efforts to ensure vaccine safety. It has been committed to using preservative-free vaccines for its Vaccines for Children programs, beginning in 1999. However, for the reasons cited above for specific vaccines, it is imperative that the people of Illinois continue to have access to life-saving vaccines when necessary, without potential compromise to health and safety. If you have questions about this Declaration of Exemption, please contact Marilyn Thomas, Chief Counsel (Acting), 217-782-2043 or TTY (for hearing impaired use only) 800-547-0466. For questions about Illinois immunization requirements, please contact Karen McMahon, Immunization Program Administrator, 217-785-1455.

Sincerely,

A handwritten signature in black ink that reads "Eric E. Whitaker M.D." with a stylized flourish at the end.

Eric E. Whitaker, M.D., M.P.H.
Director

KM:kjm