Illinois Department of
PUBLIC HEALTH

Pat Quinn, Governor
LaMar Hasbrouck, MD, MPH, Director

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

July 3, 2012

Dear Health Care Provider:

On January 1, 2006, Public Act 94-0614, Mercury-Free Vaccine Act, became effective requiring vaccines to be mercury-free except for trace amounts. On January 1, 2008, the Act was amended to state "no person shall be vaccinated with a vaccine or injected with any product that contains, or prior to dilution, had contained as an additive, any mercury based product, whether at preservative or trace amount levels." Effective July 1, 2012, the Illinois Department of Public Health filed a statewide Declaration of Exemption on behalf of public and private health care providers for the following vaccines affected by the Act: Japanese Encephalitis, Tetanus and Diphtheria Toxoids Adsorbed, tetanus toxoid, DTaP (Tripedia®), Meningococcal Polysaccharide vaccine and the Multi-dose Formulation of Influenza vaccines for the 2012-2013 influenza season. The Declaration of Exemption is attached and is also available on the Department's website http://www.idph.state.il/us/about/shots.htm. Please note that the Exemption as it relates to DTaP (Tripedia®) is applicable only until October 15, 2012.

The Illinois Department of Public Health has long supported and continued efforts to ensure vaccine safety and implemented policies to use preservative-free vaccines for its Vaccines For Children programs, beginning in 1999. In accordance with the Act, it is the policy of the Department to preferentially distribute thimerosal free influenza vaccine to children ages 3 years and under, as served through its Vaccines for Children (VFC) Program. However, for the reasons identified in the attached Declaration of Exemption for specific vaccines, it is imperative that the people of Illinois continue to be allowed access to life-saving vaccines when necessary, without potential compromise to health and safety.

If you have any questions about Illinois immunization requirements, please contact Carol Gibson Finley, Assistant Chief of the Immunization Section, 217-785-1455 or or TTY (for hearing impaired use only) 800-547-0466.

Sincerely,

LaMar Hasbrouck, MD, MPH
Director

Attachment

ILLINOIS DEPARTMENT OF PUBLIC HEALTH

MERCURY-FREE VACCINE ACT EXEMPTION DECLARATION

NOW COMES, the Department of Public Health (hereinafter, the "Department"), by and through LaMar Hasbrouck, Director, pursuant to the Mercury-Free Vaccine Act, 410 ILCS 51/1 et seq. sets forth this Exemption Declaration, and herein, states as follows:

RECITALS

WHEREAS, pursuant to the Department of Public Health Act, 20 ILCS 2305/2, the Department "has general supervision of the interests of the health and lives of the people of the State" of Illinois; and

WHEREAS, pursuant to the Communicable Disease Prevention Act, 410 ILCS 315/2, the Department has been charged with upholding "the public policy of this State that all children shall be protected, as soon after birth as medically indicated, by the appropriate vaccines and immunizing procedures to prevent communicable diseases which are or which may in the future become preventable by immunization"; and

WHEREAS, the State of Illinois has recognized and acknowledged through the Communicable Disease Prevention Act, 410 ILCS 315/1, that the general usage of "effective, safe and widely used vaccines and immunization procedures have been developed and are available to prevent ...diseases and to limit their spread"; and

WHEREAS, historically in Illinois, local health departments and private providers have provided immunization services to adults, children and other high risk individuals since the mid-1970's. The vaccines are purchased by the individual providers or local health departments with local funds; and

WHEREAS, the Mercury-Free Vaccine Act, 410 ILCS 51/5, has set forth that any mercury-containing vaccines that contain more than 1.25 micrograms of mercury per dose are to be banned commencing on January 1, 2006; and

WHEREAS, the Mercury-Free Vaccine Act, 410 ILCS 51/5, has set forth that no person shall be vaccinated with a vaccine or injected with any product that contains, or prior to dilution, had contained as an additive, any mercury based product, whether at preservative or trace amount levels.

WHEREAS, the Mercury-Free Vaccine Act at 410 ILCS 51/10 also provides that the Department "may exempt the use of a vaccine from this Act if the Department finds

that an actual or potential bio-terrorist incident or other actual or potential public health emergency, including an epidemic or shortage of supply of a vaccine at a reasonable cost that would prevent a person from receiving the needed vaccine ... " makes necessary the exemption;

WHEREFORE, after conducting a review of vaccines containing thimerosal, the Department Hereby Declares an EXEMPTION to the Mercury-Free Vaccine Act for use of each of the following vaccines: Japanese Encephalitis (JEV); Tetanus and Diphtheria Toxoids Adsorbed (Td); tetanus toxoid (TT); Diphtheria-Tetanus (DT); Diphtheria Toxoid-Tetanus Toxoid-Acellular Pertussis (DTaP [Tripedia®]), Meningococcal Polysaccharide (MPSV4) and multi-dose formulations of Influenza vaccines for the 2012-2013 influenza season.

IN SUPPORT of this Exemption to the vaccines, the Department states as follows:

In evaluating the basis for the Exemption for each of the vaccines, the Department established that the vaccine was procured either directly from the manufacturer, or via a distributor/reseller. Current manufacturing processes limit the total amount of preservative-free product that is currently available to private and public sector providers.

<u>The Department's review of Japanese Encephalitis Vaccine, (hereinafter referred to as "JEV")</u>
The JEV formulation contains thimerosal in quantities greater than those allowable by the Mercury-Free Vaccine Act. Information provided by the vaccine supplier states there are no plans to change the current JEV formulation. JEV is targeted to a specific at-risk population and must be available to immunize persons traveling to areas where Japanese Encephalitis is epidemic or endemic. The Department finds that there exists a shortage of supply of thimerosal -free JEV at a reasonable cost to meet the needs of the people of the State of Illinois such that an exemption for use of the vaccine is necessary.

<u>The Department's review of Tetanus and Diphtheria Toxoid Vaccine (hereinafter referred to as "Td") AND Diphtheria and Tetanus Toxoid Vaccine (hereinafter referred to as "DT") AND Tetanus Toxoid Vaccine (hereinafter referred to as "TT")</u>
Based upon information provided by the vaccine manufacturers, Td Vaccine is available in a single-dose, pre-filled, preservative-free formulation. The Department no longer distributes the preservative-containing product in its Vaccines for Children (VFC) program in order to assure compliance with the Mercury Free Vaccine Act. However, the Department is aware that private providers in Illinois do have the ability to purchase and administer tetanus containing vaccines, including tetanus toxoid, referred to as TT and Diphtheria-Tetanus vaccine, referred to as DT vaccine, particularly in the hospital emergency department setting for wound management and in public health emergencies. It is not possible to determine availability or current usage of any

preservative-free products for private provider practice needs. These products currently contain preservatives in excess of 1.25 micrograms and must be exempted to assure protection of those requiring these products according to physician's medical judgment. Therefore, the Department finds that there exists a shortage of supply of mercury-free Td vaccine at a reasonable cost to meet the needs of the people of the State of Illinois, such that an exemption for use of the vaccine is necessary.

The Department's review of Diphtheria Toxoid - Tetanus Toxoid - Acellular Pertussis (DTaP) Vaccine (hereinafter referred to as "Tripedia®")

The Tripedia® vaccine is a combination vaccine that protects children against diphtheria, tetanus, and pertussis. Although considered thimerosal-free by the FDA, Tripedia® contains trace amounts of thimerosal as a result of the production process. The Department no longer distributes this preservative-containing product in its Vaccines for Children (VFC) program in order to assure compliance with the Mercury Free Vaccine Act. Although sanofi pasteur ceased production of Tripedia® in January 2012, private health care providers may still possess this product for distribution and use in their patient populations. As Illinois continues to have community -based epidemics of pertussis, the supply of Tripedia® product in the possession of private health care providers is needed to reduce the risk of pertussis and to ensure that children receive their DTaP school entrance- required immunization without delay. Therefore, the Department finds that until October 15, 2012 there exists a shortage of supply of preservative-free Tripedia® vaccine at a reasonable cost to meet the needs of the people of the State of Illinois such that an exemption for the use of the vaccine is necessary.

The Department's review of Meningococcal Polysaccharide Vaccine (hereinafter referred to as "MPSV4")

Based on information from the manufacturer, MPSV4 is currently produced in a single dose and multi-dose presentation. The preservative contained in the multi-dose presentation exceeds 1.25 micrograms. The Department does not distribute the preservative-containing product in its Vaccines for Children (VFC) program in order to assure compliance with the Mercury Free Vaccine Act. However, it is unknown how much single dose formulation is available to both public and private providers in Illinois. In the event of an outbreak of meningococcal disease (i.e. university setting), it is critical to provide prevention and protection of at-risk individuals with a readily available product. Delays in procuring a preservative-free formulation may result in illness and death of exposed individuals. There are currently two manufacturers of preservative-free Meningococcal conjugate (MCV4) vaccines. While routine use of MPSV4 is not necessary, it is a valuable product to conduct outbreak control activities such as in a mass vaccination situation and thus, should be available to health care providers. The Department finds that that there exists a potential shortage of supply of MCV4 at reasonable costs to meet the needs of the people of the State of Illinois, such that an exemption for the use of the multi-dose presentation of MPSV4 is necessary.

The Department's review of Influenza Vaccines - 2012-2013 multi-dose formulation (hereinafter referred to as "Influenza Vaccine")

It is the Department's policy that it will preferentially distribute thimerosal -free influenza vaccine to children under 3 years of age as available from the Centers for Disease Control (CDC) for the VFC program. The Department procures influenza vaccine for the VFC program from the CDC through a federal contract with the manufacturer. Current manufacturing processes limit the total amount of preservative-free product that is currently available to private and public sector providers nationwide. For VFC program needs, the Department annually submits order for 100% preservative-free product to serve children under age 3 and for most children up to age eighteen years who are enrolled in the VFC Program. Additionally, the Department has increased its VFC order for Live Attenuated Influenza Vaccine (Flumist) to expand the use of preservative-free products for children.

The 2012–2013 trivalent vaccines will contain an A/California/7/2009 (H1N1)-like virus, an A/Victoria/361/2011 (H3N2)-like virus and a B/Wisconsin/1/2010-like virus (from the B/Yamagata lineage of viruses). It is not known at this time what the manufacturers' yield of vaccine will be for the 2012-2013 season. Therefore, IDPH cannot predict if the vaccine supply will be sufficient to serve all individuals eligible through the VFC program without the use of some thimerosal containing formulations. It is expected that the CDC will not be able to fulfill the Department's order because the amount of preservative-free vaccine requested by federal grantees always exceeds the amount of thimerosal preservative-free vaccine available under the federal contract and thus, the CDC instituted an allocation formula to ensure equitable distribution to all grantees. It is unknown what the final percentage will be until the manufacturing process is completed.

As a result of the reduced allocation, the Department will have insufficient vaccine supply available to serve all individuals eligible through the VFC program without the use of thimerosal containing formulations. In addition, anyone over 3 years of age, including high risk adults and senior citizens would not have access to influenza vaccine without the use of thimerosal containing products administered by their primary health care provider. The manufacturer does not reserve preservative-free influenza vaccine doses for any state, and it cannot target the vaccine for any one state. Therefore, the Department finds that there exists a shortage of supply of preservative-free influenza vaccine at a reasonable cost to meet the needs of the people of the State of Illinois such that an exemption for the use of the vaccine is necessary.

The vaccine dosage and thimerosal concentration are as follows:

Vaccine	**Trade Name**	**Manufacturer**	**Thimerosal Concentration[1]**	**Mercury**
DTaP	Tripedia®[2]	sanofi pasteur	≤ 0.00012%	≤ 0.3 µg/0.5 mL dose

DT	No Trade Name	sanofi pasteur	< 0.00012% (single dose)	< 0.3 µg/0.5mL dose
	No Trade Name	sanofi pasteur	0.01% (multi dose)	25 µg/0.5 mL dose
Td	No Trade Name	MassBiologics	≤ 0.00012% (multi dose)	≤ 0.3 µg mercury/0.5 ml dose
	Decavac	sanofi pasteur	≤ 0.00012% (single dose)	≤ 0.3 µg mercury/0.5 ml dose
TT	No Trade Name	sanofi pasteur	0.01%	25 µg/0.5 mL dose
Seasonal Trivalent Influenza	Afluria	CSL Limited	0.01%	24.5 µg/0.5 mL
	Fluzone [3]	sanofi pasteur	0.01%	25 µg/0.5 mL dose
	Fluvirin	Novartis	0.01%	25 µg/0.5 ml dose
	Fluvirin (Preservative Free)	Novartis	< 0.0004%	< 1 µg/0.5 mL dose
	Fluarix (adult)	GlaxoSmithKline	< 0.0004%	< 1 µg/0.5 ml dose
	FluLaval	GlaxoSmithKline	0.01%	25 µg/0.5 ml dose
Japanese Encephalitis	JE-VAX	sanofi pasteur	0.007%	35 µg/1.0mL dose 17.5 µg/0.5 mL dose
Meningococcal	Menomune A, C, AC and A/C/Y/W-135	sanofi pasteur	0.01% (multidose) 0 (single dose)	25 µg/0.5 dose(multidose) 0(single dose)

Table Footnotes

1. Thimerosal is approximately 50% mercury (Hg) by weight. A concentration of 1:10,000 is equivalent to a 0.01% concentration and contains 25 µg of Hg per 0.5 ml dose.
2. Sanofi Pasteur's Tripedia® may be used to reconstitute ActHib to form TriHIBit. TriHIBit is indicated for use in children 15 to 18 months of age.
3. Children 1 to 3 years of age receive a half-dose of vaccine (12.5 µg/0.25 mL dose)

The Department supports efforts to ensure vaccine safety and it has been committed to using preservative-free vaccines in its Vaccines for Children programs since 1999; however, it finds that an exemption for use of the above listed vaccines is necessary due to evidence that insufficient supplies of these vaccines are available at a reasonable cost. Without the exemption, this shortage of supply would prevent persons in the State of Illinois from receiving the needed vaccines and reasonably constitutes an actual or potential public health emergency under the Mercury-Free Vaccine Act, 410 ILCS 51/10.

Accordingly, the Department, by and through its Director, pursuant to Section 10 of the Mercury-Free Vaccine Act, hereby exempts the use of the following vaccines: Japanese Encephalitis; Tetanus and Diphtheria Toxoids Adsorbed; tetanus toxoid; Diphtheria-Tetanus; DTaP (Tripedia®); Meningococcal Polysaccharide; and Influenza Vaccine – 2012-2013 multi-dose formulation from the requirements of the Mercury-Free Vaccine Act. This Exemption is applicable from July 1, 2012

until June 30, 2013, with the exception of the DTaP (Tripedia®) vaccine which is applicable until October 15, 2012. This Exemption may be reissued or amended upon further determination by the Department.

LaMar Hasbrouck, MD, MPH
Director, Illinois Department of Public Health

July3, 2012
Date