

ILLINOIS DEPARTMENT OF PUBLIC HEALTH

**MERCURY-FREE VACCINE ACT
EXEMPTION DECLARATION**

NOW COMES, the Department of Public Health (hereinafter, the "Department"), by and through Nirav D. Shah, 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 ... 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: Diphtheria-Tetanus (DT); Tetanus and Diphtheria Toxoids (Td); Tetanus Toxoid (TT); multi-dose formulation of Meningococcal Polysaccharide (MPSV4) vaccine and multi-dose formulations of Influenza vaccines for the 2015-2016 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.

The Department's review of Diphtheria and Tetanus Toxoid Vaccine (DT); Tetanus and Diphtheria Toxoids Vaccine (Td); and Tetanus Toxoid Vaccine (TT):

Based on information provided by the vaccine manufacturers, Td Vaccine is available in a single-dose, pre-filled, thimerosal-free formulation while multi-dose formulations do contain thimerosal. Neither DT nor TT is available in a thimerosal-free formulation. The Department no longer distributes the preservative-containing Td 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 DT vaccine, Td vaccine and TT 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. Some of these products currently contain preservatives 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 an actual or potential shortage of supply of thimerosal-free DT, Td and TT 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 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 limit. The Department does not distribute the preservative-containing product in the 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. school or 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 three 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 there exists an actual or 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 - 2015-2016 multi-dose formulation (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 orders for 100% preservative-free product to serve children under age 3 and for most children the 18 years of age who are enrolled in the VFC Program. This includes the Department's VFC orders for Live Attenuated Influenza Vaccine (Flumist), which is a preservative-free product.

It is not known at this time what the manufacturers' yield of vaccine will be for the 2015-2016 season. Therefore, the Department 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 full request for preservative-free vaccine because the amount of preservative-free vaccine requested by all federal grantees always exceeds the amount of thimerosal preservative-free vaccine available under the federal contract. As a result, the CDC has instituted an allocation formula to ensure equitable distribution to all grantees. It is unknown what percentage of preservative-free vaccine Illinois will receive until the manufacturing process is completed.

As a result of the actual or potential reduced allocation, the Department may have insufficient vaccine supply of thimerosal-free vaccine available to serve all individuals eligible through the VFC program. 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 influenza vaccine manufacturers do not reserve preservative-free influenza vaccine doses for any state, and cannot target the vaccines for any one state. Therefore, the Department finds that there exists an actual or potential shortage of supply of thimerosal-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
DT	No Trade Name	Sanofi Pasteur, Inc.	< 0.00012% (single dose)	< 0.3 µg/0.5mL dose (single dose)
	No Trade Name	Sanofi Pasteur, Inc.	0.01% (multi-dose)	25 µg/0.5 mL dose (Multi-dose)
Td	No Trade Name	MassBiologics	≤ 0.00012%	≤ 0.3 µg mercury/0.5 ml dose
	Decavac (Multi-dose)	Sanofi Pasteur, Inc.	≤ 0.00012%	≤ 0.3 µg mercury/0.5 ml dose Multi-dose Vial
TT	No Trade Name	Sanofi Pasteur, Inc.	0.01%	25 µg/0.5 mL dose
Seasonal Trivalent Influenza	Afluria (Multi-dose)	CSL Limited	0.01%	24.5 µg/0.5 mL Multi-dose
	Fluzone (Multi-dose)	Sanofi Pasteur, Inc.	0.01%	25 µg/0.5 mL dose Multi-dose
	Fluvirin (Multi-dose)	Novartis	0.01%	25 µg/0.5 ml dose Multi-dose
	FluLaval (Multi-dose)	GlaxoSmithKline	0.01%	25 µg/0.5 ml dose Multi-dose Vial
Meningococcal	Menomune A, C, AC and A/C/Y/W-135 (Multi-dose)	Sanofi Pasteur, Inc.	0.01%	25 µg/0.5 dose Multi-dose Vial

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. Children 1 to 3 years of age receive a half-dose of vaccine (12.5 µg/0.25 mL dose)

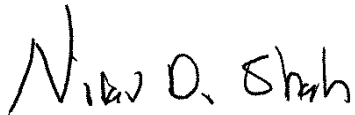
The Department supports efforts to ensure vaccine safety and it has been committed to using thimerosal-free vaccines in the VFC program since 1999; however, it finds that an exemption for use of the above listed vaccines is necessary due to evidence that insufficient supplies of these vaccines are available at a reasonable cost. Without the exemption, this actual or potential 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 from the requirements of the Mercury-Free Vaccine Act:

**Diphtheria and Tetanus Toxoids (DT);
Tetanus and Diphtheria Toxoids (Td);
Tetanus Toxoid (TT);
Meningococcal Polysaccharide Vaccine (MPSV4) in multi-dose formulation;
and
Influenza Vaccine - 2015-2016 in multi-dose formulation**

This Exemption is applicable for 12 months from the date of signature, and may be reissued or amended upon further determination by the Department.



Nirav D. Shah, M.D., J.D.
Director, Illinois Department of Public Health

June 24, 2015

Date