

# MAINE STATE LEGISLATURE

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John Elias Baldacci  
Governor

## Maine Department of Health and Human Services

Maine Center for Disease Control and Prevention  
(Formerly Bureau of Health)  
286 Water Street  
11 State House Station  
Augusta, ME 04333-0011

John R. Nicholas  
Commissioner

Dora Anne Mills, MD, MPH  
Public Health Director  
Maine CDC Director

January 15, 2006

Senator Arthur F. Mayo III, Co-Chair  
Representative Hannah Pingree, Co-Chair  
Committee on Health and Human Services  
State House  
Augusta, ME 04333

Re: LD 148, An Act To Require Certain Physicians To Provide Information about  
Thimerosal in Vaccines

Dear Senator Mayo, Representative Pingree, and Members of the Committee:

This is a report to you, as requested as a result of LD 148, to inform you about our efforts to educate health care providers and the public on thimerosal preservative found in some vaccinations. The following activities have taken place since spring, 2005 by the Maine Center for Disease Control and Prevention (Maine CDC, formerly Bureau of Health):

1. We developed a Power Point presentation on thimerosal and vaccines – see attachment.
2. We developed a one-page fact sheet on thimerosal and vaccines – see attachment.
3. We posted both the Power Point and fact sheet on our website's home page ([www.mainepublichealth.gov](http://www.mainepublichealth.gov)).
4. I made a 30-minute presentation before 300 attendees of our annual Immunization Conference in May, 2005 on thimerosal and vaccines, using the Power Point. We disseminated copies of the Power Point and the fact sheet to all attendees.
5. I made several other presentations of the Power Point, including at the annual meeting of the Maine Public Health Association and at some medical meetings.
6. We disseminated the fact sheet and link to the Power Point by fax to all vaccine providers (~1,200 providers) and to the American Academy of Pediatrics Maine Chapter list serve.

*Our vision is Maine people enjoying safe, healthy and productive lives.*  
[www.mainepublichealth.gov](http://www.mainepublichealth.gov)

7. We wrote an article for the summer issue of the Epigram with linkages to the fact sheet and Power Point (disseminated to ~2,000 providers).
8. I did a number of media interviews on the subject of thimerosal and vaccines, including an aired 12-minute interview with me and author David Kirby on channel 6/2 show "207" and a one-hour cable tv show aired throughout southern Maine on cable access tv stations with Rep. Glynn.
9. We produced a 15-minute tv interview format show on the subject for airing this winter on cable access stations throughout the state.
10. I wrote an article on thimerosal and vaccines that was printed in Maine newspapers.
11. We plan on continuing to inform health care providers, parents, and the public on the safety of vaccines and to answer their questions about thimerosal.

Sincerely,

A handwritten signature in cursive script that reads "Dora Anne Mills".

Dora Anne Mills, MD, MPH  
Director, Maine CDC

# **Thimerosal Fact Sheet**

## ***What Is Thimerosal?***

- It is a preservative used in 30 types of vaccines for 60 years.
- Used in multi-dose vials, it prevents bacterial and fungal contamination.
- It contains ethylmercury, a form of mercury that is probably less toxic and cleared faster from the body than methylmercury, the type of mercury found in some fish (swordfish, tuna).

## ***Do Childhood Vaccines in Maine Contain Thimerosal?***

- Recommended vaccines for young children in Maine do not contain thimerosal.<sup>1</sup>

## ***When Did Thimerosal Come to National Attention and What Did Maine Do?***

- In 1999, when the presence of thimerosal in vaccines was highlighted in a report by the U.S. Food and Drug Administration, the Maine Bureau of Health (now Health and Human Services' Public Health) moved quickly to assure that all childhood vaccines provided by them were thimerosal-free whenever possible.
- Since 2002, all recommended childhood vaccines have been thimerosal-free except for influenza vaccine. However, as of the 2005 flu season, influenza vaccine for children under 3 is also thimerosal-free.

## ***Is Thimerosal Used In Any Vaccines?***

- Some vaccines that are primarily for older children and adults are not available yet without thimerosal.
- Because those with small body weights and developing brains are most susceptible to mercury's effects, the first priority is to reduce mercury exposure in young children.
- Thimerosal-containing vaccines may be unavoidable in epidemics and in other situations where multi-dose vials are needed.

## ***Is Thimerosal Associated with Autism?***

- Six studies from Denmark, Sweden, United Kingdom, and the United States show no association between thimerosal in vaccines and autism.
- For example, after thimerosal was discontinued in the early 1990s in Denmark and Sweden, autism did not decline.
- However, it is clear there is a great need for broad research to determine the causes of and effective treatments for autism.

## ***Where Can I Find Additional Information?***

- [www.mainepublichealth.gov](http://www.mainepublichealth.gov) and [www.cdc.gov](http://www.cdc.gov) and [www.fda.gov](http://www.fda.gov)

**There are no known long-term risks of thimerosal when given in vaccine,  
but there are very known risks of not vaccinating.**

*Dora Anne Mills, MD, MPH Director  
Maine Health and Human Services' Public Health  
October, 2005*

If you have further concerns or comments, please call Maine Immunization Program at  
1-800-867-4775

<sup>1</sup> Occasionally, DtaP or Hepatitis B vaccines may have trace amounts of thimerosal left over from the manufacturing process.

## Thimerosal



Dora Anne Mills, MD, MPH  
Maine Health and Human  
Services' Public Health  
Director

September 21, 2005

## Thimerosal



- Is a preservative containing ~49% ethylmercury;
- Has been used in vaccines and other pharmaceuticals (ophthalmic and nasal products ) since the 1930's;
- Assures non-contamination from bacteria;
- Is necessary in most multi-dose vials;
- When not used, single dose vials are necessary.

## 1999



- FDA asked by Congress in 1997 to study exposures to mercury.
- Summer 1999, FDA announced infants might be exposed to cumulative doses of ethylmercury through Thimerosal in vaccines that exceeded guidelines established for methylmercury by EPA and ATSDR (for small infants only).
- FDA and WHO guidelines not exceeded.
- Two studies suggested linkage between childhood vaccines and autism - one focused on MMR and one on the rise of infant vaccines in the 1990's, along with a rise in autism.

## 1999



- The Bureau of Health was started in July, 1999 to provide Thimerosal-free vaccine whenever possible.
- Nationally, by March 2001, all formulations of vaccines for 6 years and younger became available Thimerosal-free, with last expiration dates of TCV (Thimerosal-containing vaccine) in 2002.



Exposure to Mercury from Vaccines 1999 vs. 2005 (for children)		
	1999 Max. Mercury ( $\mu\text{g}$ )	2005 Max. Mercury ( $\mu\text{g}$ )
Infants <6 months	188	Trace ( $<<2.4$ )
Children <2 years	275	Trace ( $<<2.4$ )

### Mercury

- Is a heavy metal (as is Lead = Pb);
- Can bind to proteins;
- Central nervous system and kidney are primary sites of toxicity;
- Children are most susceptible to toxicity (low body weight and developing nervous system);
- Three common types of mercury: Elemental, Inorganic, and Organic (methyl and ethyl);
- The 3 types of mercury differ in toxicity and toxicokinetics (they are not equal).

### Elemental Mercury

- Used in thermometers, barometers, dental amalgam
- Well-absorbed if inhaled
- Poorly absorbed if ingested or handled.

### Organic Mercury - Methylmercury

- Found in fish -> Bureau of Health's Fish Consumption Advisories.
- Pollution releases elemental mercury from smokestack precipitates and forms organic mercury once in watersheds, accumulating in fish.
- People eating some fresh fish ingest methylmercury, which is readily absorbed and can cross the blood-brain barrier.
- One can of white tuna per week -> 6-8 micrograms methylmercury per day (half for light canned tuna).



## Organic Mercury - Ethylmercury

- In Thimerosal.
- Limited toxicological data on this type of mercury.
- Studies indicate:
  - Thimerosal accumulates in the blood and brain to a much lower degree than methylmercury.
  - Ethylmercury is eliminated from infants rapidly from blood via stools after TCV (Thimerosal-Containing Vaccine) is administered.



## 2004 Institute of Medicine (IOM) Report

- Studied possible relationship between thimerosal in vaccines and autism.
- "The committee concludes that the evidence favors rejection of a casual relationship between thimerosal-containing vaccines and autism."



## Autism – What Is It?

- Complex set of developmental disorders with impairments in social interaction, verbal and non-verbal communication, repetitive patterns of behavior.
- PDD (Pervasive Developmental Disorders) and ASD (Autistic Spectrum Disorder) are often used interchangeably with "Autism", but refer to a broader group of disorders, including autistic disorder, Asperger's syndrome, Rett's syndrome, and childhood disintegrative disorder.
- Different forms of Autism:
  - Early Onset type (majority of autism), with symptoms apparent on retrospective infant videos, but diagnosis usually made at 2-3 years of age;
  - Regressive type (much rarer), with normal development followed by failure to progress or regression in development.



## Autism – How Common Is It?

- Prevalence ~10/10,000.
- Increasing prevalence? Some studies suggest autism is increasing.
- CA study showed rates increased 5.8 to 14.9 per 10,000 from 1987 to 1994 birth cohorts, using children registered in CA Developmental Services system.
- However, consistent case definitions and other methodological challenges make assessing trends difficult.
- Numbers do not reflect large impact of autism on families and society.



### Autism – What Are the Possible Causes?

- **Genetics** – plays a role, since high rates among twins (90% among identical twins) and other siblings (50-100 higher rates among siblings).
- **Early Gestational Insults** – some pathophysiological evidence for this.
- **Immune Dysregulation** – some evidence shows associated findings, but unclear if they are part of the syndrome or a cause of it.
- **Abnormal Mercury Metabolism** – autism not shown to be associated with mercury exposure.
- **Thimerosal Neurotoxin Effects** – no evidence of this from epidemiological studies.
- **Pharmacogenetics** – genetic susceptibility to pharmacological effects, would be difficult to detect in epidemiological studies.



### Status of Thimerosal in Vaccines

- Thimerosal use in vaccines has diminished greatly since 1999, especially in childhood vaccines.
- The maximum amount of ethylmercury an infant in the U.S. exposed to through routine childhood immunizations was 188 micrograms in 1999, and is now < 3 micrograms.
- All routine childhood vaccines provided by the Bureau of Health are now considered free of Thimerosal except for trace amounts found in 3 of them.



### Autism – Challenges to Research

- Uncertain prevalence and incidence trends
- Changing case definitions
- Little knowledge of natural history of autism
- No strong biological model for autism
- Lack of diagnostic biomarkers
- Limited understanding of associated features – immune and gastrointestinal

**Need more research on causes and treatment of autism!!**



### MMR Vaccine and Autism

- 1998 Wakefield Study retrospective case series of 12 children with autism
- Retrospective interviews – association of MMR with onset of symptoms in 8 children
- Study stated it showed no proven association
- MMR is live virus vaccine – no thimerosal
- Since 1998, numerous studies published, all showing no association between MMR and autism.
- 2004 IOM Report: “favors rejection of a casual relationship between the MMR vaccine and autism”





## Studies Regarding Thimerosal-Containing Vaccines (TCV) and Autism



### Geier & Geier US 2003 & 2004 on Vaccine Distribution and DOE Data

- Compared distributed vaccine doses in U.S. and caseloads of autistic children reported to U.S. Department of Education (DOE) for birth cohorts 1981-1985 and 1990-1996.
- Concluded autism increased six-fold during this time.

### Geier & Geier US 2003 on Vaccine Distribution and DOE Data

- Using distributed vaccine doses to determine birth cohort thimerosal exposure (each year 1984-1985, 1990-1994), compared exposure to U.S. Department of Education (DOE) reports on autism.
- Found dose-response of thimerosal to autism.



### Serious flaws of Geier and Geier studies, including:


- No way of knowing individual children's thimerosal exposure in order to determine dose response, since the data used were the number of doses of vaccine distributed nationwide per year (not doses administered) and these data do not provide information on distribution of vaccine by age group or birth cohort. In other words, the number of vaccines distributed in 1984 may not be the same number of doses received by children born that year.
- DOE data is a point in time number of all school children served for autistic services, not a good proxy for prevalence since states use different definitions for autism to determine eligibility for services. Also, autistic children in this database were reported in a different disability category 1990, and these data cannot be converted to birth-cohort prevalence as done.




### Serious flaws of Geier and Geier studies (cont'd):

- The descriptions of the analytical methods omitted many details – no specifications of the regression models used, frequency of distribution of variables not provided, and calculations not clear or not reported.

IOM found the Geier and Geier studies to be "uninterpretable and, therefore, non-contributory with respect to causality".



- DTaP, Pediatric Influenza, and occasionally Hepatitis B can contain a trace of Thimerosal that is left over from the manufacturing process.
- There may be a Thimerosal-free, preservative-free pediatric influenza vaccine for 2005-2006.
- Adult Influenza Vaccine, when given as a half-dose to children, contains 12.5 micrograms of ethylmercury.
- CDC is proposing to add information on Thimerosal to Vaccine Information Statements.



### What to Tell Concerned Parents

- There are no known long-term risks of Thimerosal when given in vaccines.
- Thimerosal use has diminished greatly since 1999 (with ethylmercury exposure from 188 micrograms to a maximum of <3 from routine infant immunizations).
- No known long-term risks for Thimerosal, versus known risks of non-immunization.