

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 491 Immunizations
SPONSOR(S): Goldstein and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 82

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|---|--------|----------|----------------|
| 1) Health Care General Committee | _____ | Halperin | Brown-Barrios |
| 2) Health Care Regulation Committee | _____ | _____ | _____ |
| 3) Health Care Appropriations Committee | _____ | _____ | _____ |
| 4) Health & Families Council | _____ | _____ | _____ |
| 5) _____ | _____ | _____ | _____ |

SUMMARY ANALYSIS

HB 491 prohibits, on and after July 1, 2007, the use of vaccines that contain more than specified amounts of mercury in immunizing knowingly pregnant women or children younger than 3 years of age.

The bill provides two exceptions in which knowingly pregnant women or children younger than 3 years of age may receive vaccines containing more mercury than the maximum level established in the bill. These exceptions include

- (1) declared public health emergencies, and
- (2) situations where a health care practitioner suggests that the benefits of a patient receiving a vaccine containing more mercury than the maximum established level outweigh the risks of mercury exposure, and the patient consents to receiving such a vaccine.

If enacted, the bill takes effect on the date it becomes law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government: The bill creates additional statutory requirements and regulations for certain health care practitioners.

B. EFFECT OF PROPOSED CHANGES:

The bill prohibits, on or after July 1, 2007, the use of vaccines that contain more than specified amounts of mercury in immunizing knowingly pregnant women or children younger than 3 years of age. For influenza vaccines, the bill prohibits more than 1 microgram of mercury per 0.5-milliliter dose in vaccines administered to the target population. For all other vaccines, the bill prohibits more than 0.5 micrograms of mercury per 0.5 milliliter dose in vaccines administered to the target population.

The bill provides two exceptions in which knowingly pregnant women or children younger than 3 years of age may receive vaccines containing more mercury than the maximum level established in the bill. These exceptions are:

- (1) If the Secretary of Health declares a public health emergency and finds that an epidemic or shortage of supply of a vaccine will prevent knowingly pregnant women or children younger than 3 years of age from receiving the needed vaccine, the State Health Officer may authorize the administration of vaccine that contains more mercury than the maximum level established in the bill.¹
- (2) If according to the judgment of a licensed health care practitioner suggests, based on accepted medical standards, the benefits of the patient receiving the vaccine to prevent a vaccine-preventable disease outweigh the risks of mercury exposure. Before administering the vaccine, the practitioner must provide the patient or legal guardian with information concerning the risks and benefits of the vaccination.

This bill will not change:²

- The Department of Health's (DOH) vaccine requirements;
- The administration of required vaccines to children or pregnant women;
- Standard DOH procedure in declaring or during a public health emergency; and
- The federally required use of Vaccine Information Statements that are given to patients whenever certain vaccinations are given.

¹ Section 381.00315, F.S., provides processes for the declaring of public health emergencies.

² From the Department of Health Bill Analysis, Economic Statement, and Fiscal Note on HB 491, 12/ 22/2005.

Current Efforts to Reduce Mercury Exposure in Pharmaceuticals and Vaccines

The Food and Drug Administration (FDA) is encouraging the reduction or removal of mercury from all existing vaccines, and is working with drug manufacturers and other public health agencies to accomplish this elimination.³ Manufacturers are working to increase the supply of mercury-reduced and mercury-free vaccines used to immunize children and pregnant women against the influenza virus. To date, mercury-based preservatives have been removed or reduced to trace amounts in nearly all pharmaceuticals and pediatric vaccines; though it remains in a few required childhood shots. According to the FDA, much progress has been made in removing or reducing mercury in vaccines. Merck, Glaxo SmithKline, and Aventis Pasteur have all been licensed to develop various mercury-free vaccines. Currently, all routinely recommended vaccines for U.S. infants are available only as mercury-free, or contain only trace amounts, with the exception of the inactivated influenza vaccine. Inactivated influenza vaccines for pediatric use are available in preservative-free formulations, but are in more limited supply.⁴

Legislation to ban thimerosal from childhood vaccines has passed in seven states: New York, Tennessee, Iowa, Delaware, Illinois, Missouri, and California. Legislation in Congress (HR 881) has been introduced by Rep. Dave Weldon, M.D. (R-Florida) and Carolyn Maloney (D-NY).⁵

Florida Immunization Requirements

Section 1003.22, F.S., authorizes the Department of Health, after consultation with the Department of Education, to adopt administrative rules, that conform to recognized standards of medical practice, governing the immunization of children against, the testing for and the control of preventable communicable diseases. The department must supervise and enforce requirements, and must provide required vaccines at no cost from county health departments. Section 402.305, F.S., requires child care facilities to comply with immunization rules as a condition for licensing. Section 414.13, F.S., requires each applicant for cash assistance programs who has a preschool child to begin and complete appropriate childhood immunizations for the child as a condition of eligibility. Florida law requires immunizations for poliomyelitis, diphtheria, rubella, pertussis, mumps, tetanus, and other communicable diseases as determined by the rules of the Department of Health.⁶ The recommended childhood immunization schedule in Florida includes⁷:

| Vaccine | Doses | Age(s) at Administration |
|---|--------|---|
| Diphtheria, tetanus, and pertussis vaccine (DTaP) | 5 | 2, 4, 6, and 12-18 months; and 4-5 years. |
| Polio | 4 | 2, 4, 6-18 months; and 4-5 years. |
| Measles, mumps and rubella vaccine (MMR) | 2 | 12-15 months; and at 4-5 years. |
| Hepatitis | 3 | By 12 months |
| Pneumococcal conjugate (Prevnar) | 4 | 2, 4, 6 and 12 months |
| Haemophilus influenzae type b (Hib) | 3 or 4 | By 18 months. |
| Varicella (chickenpox) | 1 | Any time after 12 months. |

³ Thimerosal as a vaccine preservative. *Weekly Epidemiology Record*. 2000; 75:12-16.

⁴ <http://www.fda.gov/cber/vaccine/intro>

⁵ HR 881

⁶ See Rule 64D-3.011, Florida Administrative Code.

⁷ Florida Department of Health, Immunization Schedule Information.

http://doh.state.fl.us/Disease_ctrl/immune/qi_clinical/clinical.html

STORAGE NAME: h0491.HCG.doc

DATE: 4/4/2006

A few of these immunizations still contain mercury-based preservatives. According to the Florida's Department of Health (DOH), vaccines which contain mercury that are administered to children and pregnant women include: Diphtheria-Tetanus (DT), Tetanus-Diphtheria (Td), Influenza, and Meningococcal vaccine. Completion of this series is required for school and child care center attendance in Florida. The inactivated influenza vaccine also contains mercury, and is recommended for children and pregnant women. In addition, adolescents are required to receive a Td booster vaccine prior to entering middle school, and these shots contain trace amounts of mercury, at levels considered safe by the CDC.

Mercury-Free Vaccines Available in Florida

DOH currently provides vaccine products with less than 0.5 mcg of mercury for children less than three years of age who receive shots at public health clinics. A Td product with less than 0.5 mcg of mercury is currently licensed for adults, including pregnant women. The Advisory Committee on Immunization Practices (ACIP) recommends vaccinating children and pregnant women against influenza disease. Currently there are both formulations of influenza vaccine that contain less mercury as a preservative as well as a preservative-free formulation. Mercury-free adult influenza vaccines are not always available in sufficient quantity for pregnant women.

Controversy Regarding Preservatives in vaccines

Regulations adopted by the United States Food and Drug Administration (FDA) require the addition of a preservative to multi-dose vials of vaccines.⁸ One common preservative is thimerosal⁹, a compound that is 50 percent mercury by weight. Thimerosal is used to prevent cross-contamination and the growth of harmful microbes.¹⁰ Specifically, mercury has been suggested to cause or contribute to the onset of neurodevelopmental disorders such as autism or speech and language delay. Autism is a severe and pervasive neurodevelopmental disorder characterized by a number of physical, language, and behavioral impairments.

Evidence suggesting mercury causes health and developmental problems

The proponents of removing mercury from vaccines point to the rise in the rate of autism and other neurodevelopmental problems. Other-environmental exposures to mercury (such as from dental amalgams, fish consumption, and other environmental means), are established as a risk to neural development.¹¹ Although the type of mercury in vaccines is ethylmercury, a cousin to the environmental form of mercury (methylmercury) research comparing the blood and brain levels of mercury in monkeys exposed to either methylmercury and ethylmercury demonstrate that thimerosal brings mercury into the brain; leaves higher levels of inorganic mercury in the brain than methylmercury; and that this inorganic mercury stays in the brain for years.¹² Research has further demonstrated that children with certain physiologies are impaired in their ability to detoxify mercury; that these conditions are common in children with autism; that concentrations of mercury in vaccines are neurologically harmful; and that boys are more 4 times more likely to have both this physiology and to have autism.¹³

⁸ See 21 CFR 610.15(a)

⁹ Thimerosal™ is a registered trademark of Eli Lilly

¹⁰ Thimerosal is not the only mercury-based compound that may be used as a preservative; therefore this analysis will refer interchangeably to "mercury" and "thimerosal"

¹¹ Clarkson, T.W. et al. "The toxicology of mercury – current exposures and clinical manifestations." *New England Journal of Medicine* 349:18. October 30, 2003.

¹² TM Burbacher, Shen DD, Liberato N, Grant KS, Cernichiari E, and Clarkson T. 2005. Comparison of blood and brain mercury levels in infant monkeys exposed to methylmercury or vaccines containing thimerosal. *Environ Health Perspect*: doi: 10. 1289/ehp.7712. (Online 21 April 2005)

¹³ Molecular Aspects of Thimerosal-induced Autism. Congressional Testimony by Richard C. Deth, Professor of Pharmacology, Northeastern University. See also Waly, M, Olteanu H, Banerjee R, et al. Activation of methionine

The incidence of autism has risen by about forty-fold in the past twenty years and now affects approximately one in every 166 births in the United States. According to the US Department of Education, autism is growing at a consistent rate of ten to 17 percent per year—meaning that about 4 million Americans will be living with autism in the next decade.¹⁴ National health agencies concur that autism is epidemic, and that increased rates represent true cases and not merely better reporting or diagnostics. A number of new mercury-containing immunizations were added to the battery of required vaccinations in the late 1980s. Proponents of the link between mercury and autism cite this fact and argue that this drastic increase in the cumulative amount of thimerosal exposure is responsible for causing the rise in the prevalence of autism.

In 1982, the FDA convened an expert panel reviewing mercury in over-the-counter products. It reported that thimerosal was “toxic, caused cell damage, was not effective in killing bacteria or halting their growth” and is not recognized as being “safe or effective.”¹⁵ In 1997, Congress passed the Food and Drug Administration Modernization Act that required the study of mercury content in FDA-approved products. The review revealed previously unrecognized high levels of mercury in the childhood vaccination schedule, in excess of the Environmental Protection Agency’s (EPA) limit for methylmercury.^{16,17}

These agency findings lead to a recommendation made in July 1999 by the Public Health Service (PHS) agencies and the American Academy of Pediatrics (AAP) that thimerosal be taken out of vaccines as a precautionary measure. The IOM’s Safety Review Committee concluded that the link between mercury and autism is “biologically plausible” and recommended that infants, children and pregnant women should not be exposed to thimerosal-containing vaccines.¹⁸

Evidence suggesting that mercury in vaccines does not causes health problems

The Institute of Medicine’s (IOM) Immunization Safety Review Committee concluded that evidence is inadequate to either accept or reject a causal relationship between thimerosal exposure from childhood vaccines and the onset of neurodevelopmental disorders, but that the link is “biologically plausible.” A later IOM committee concluded that the scientific evidence favors a rejection of a causal relationship between vaccines containing thimerosal and autism. The report also indicates that efforts to remove thimerosal from vaccines are a prudent course of action.¹⁹ The CDC recently conducted a study to see whether there are associations between vaccines containing thimerosal as a preservative and a wide range of neurodevelopmental disorders. Results found no consistent significant associations. Studies to examine these issues are ongoing.²⁰

Laboratory studies have tested the effect of mercury in vaccines on the concentrations of mercury in the blood. Although results between studies vary, mercury appeared to be eliminated from the blood rapidly via the stools after administration of vaccines.²¹ A recent study conducted by the National

synthase by insulin-like growth-factor-1 and dopamine: a target for neurodevelopmental toxins and thimerosal. *Molecular Psychiatry*. 2004; 9:358-70.

¹⁴ U.S. Department of Education's "Twenty-First Annual Report to Congress on the Implementation of the Individuals with Disabilities Education Act" (1999).

¹⁵ 1982 Vol. 47, No. 2 Federal Register

¹⁶ The FDA determined that in the absence of a specific standard for ethylmercury, standards for methylmercury should be used. According to the Congressional Record (reference below) ethylmercury should be considered equipotent to methylmercury as a developmental neurotoxin.

¹⁷ May 21, 2003. Congressional Record, Mercury in Medicine Report.

¹⁸ Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders (2001), Institute of Medicine. See also “Thimerosal in Vaccines” at <http://www.fda.gov/cber/vaccine/thimerosal.htm>.

¹⁹ Immunization Safety Review: Vaccines and Autism (2004). Board on Health Promotion and Disease Prevention (HPDP), Institute of Medicine (IOM). Available at <http://fermat.nap.edu/books/030909237X/html/>.

²⁰ <http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/thimerosal-vacs-facts.htm>

²¹ Pichichero, M. et al. 2002. “Mercury concentrations and metabolism in infants receiving vaccines containing thimerosal: a descriptive study.” *The Lancet*. Vol 360, November 30, 2002.

Institute of Allergy and Infectious Diseases (NIAID) concluded that mercury levels in the blood of babies that received vaccines with thimerosal remained well below levels considered acceptable by the EPA. Furthermore, ethylmercury thimerosal) seems to be removed from the body quickly through the gastrointestinal tract (stools).²²

A study in Denmark revealed no decrease in the prevalence of autism after thimerosal-containing vaccines were discontinued in 1992, and concludes that thimerosal plays no role in the etiology of autism.²³

In 2004, the IOM's Immunization Safety Review Committee issued its final report, examining the hypothesis that vaccines, specifically the MMR vaccines and Thimerosal containing vaccines, are causally associated with autism. In this report, the committee incorporated new epidemiological evidence from the U.S., Denmark, Sweden, and the United Kingdom, and studies of biologic mechanisms related to vaccines and autism since its report in 2001. The committee concluded that this body of evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism, and that hypotheses generated to date concerning a biological mechanism for such causality are theoretical only.²⁴

Further, the committee stated that the benefits of vaccination are proven, that the hypothesis of susceptible populations is presently speculative, and that widespread rejection of vaccines would lead to increases in incidences of serious infectious diseases like measles, whooping cough and Hib bacterial meningitis.

Research on public perception and public trust in the vaccine program

Public perception of the safety of childhood vaccines has a direct impact on immunization rates.²⁵ Thus, there are two separate problems: (1) The possible risk of thimerosal itself, and (2) The public trust in the safety of vaccines.

Some people fear that discussing the risks of mercury could cause alarm in parents and lessen their compliance with vaccine requirements, which in turn poses a threat to public health. Others suggest that leaving thimerosal in vaccines could result in the same loss of public trust. Research surveys suggest that public trust is increased when people perceive the government to be taking action to reduce risks by removing mercury from vaccines, even when those risks are not absolute.

C. SECTION DIRECTORY:

Section 1. Prohibits vaccinating a woman who is knowingly pregnant or a child who is younger than 3 years age with a vaccine that contains more than specified amounts of mercury; and provides exemptions from this requirement.

Section 2. Provides an effective date of becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

²² <http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/thimerosal-vacs-facts.htm>

²³ Madsen, KM, Lauritsen, MB, et al. 2003. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population-Based Data. *Pediatrics*. 112(3): 604-606.

²⁴ See also Madsen, KM, Lauritsen, MB, et al. 2003. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population-Based Data. *Pediatrics*. 112(3): 604-606.

²⁵ Biroscak, BJ, Fiore AE, Fasano N, et al. 2003. Impact of the thimerosal controversy on hepatitis B vaccine coverage of infants born to women of unknown hepatitis B surface antigen status in Michigan. *Pediatrics*. 107:1147-1154.

None

2. Expenditures:

The Department of Health reports that it currently orders preservative-free influenza vaccine for children aged 6 to 35 months, therefore there is no fiscal impact associated with supplying vaccine to this age group. The department noted that it could not estimate the number of pregnant women who need to be vaccinated against influenza and therefore could not accurately estimate any additional costs associated with the use of only preservative-free influenza vaccine or influenza vaccine that contains no more than 1 microgram per 0.5-milliliter dose.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Infants, children, and pregnant women may have some health benefits from a reduced exposure to mercury under the bill. There may be some increased cost associated with the purchase of preservative-free formulations, where available.

D. FISCAL COMMENTS:

There are no tax/fee issues.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill will have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

2. Other:

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required as a result of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES