F I S C A L I M P A C T R E P O R T

SPONSOR King **ORIGINAL DATE** 1-28-06 **LAST UPDATED** **HB** 271

SHORT TITLE Influenza Vaccine Supply and Contents **SB**

ANALYST Collard

APPROPRIATION (dollars in thousands)

Appropriation		Recurring or Non-Rec	Fund Affected
FY06	**FY07**		
	NFI		

(Parenthesis ( ) Indicate Expenditure Decreases)

Duplicates HJM 5

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY06	FY07	FY08	3 Year Total Cost	Recurring or Non-Rec	Fund Affected
Total	N/A	$ 223,170.0	$0.1	223,170.0	Recurring	General Fund

(Parenthesis ( ) Indicate Expenditure Decreases) See Narrative

SOURCES OF INFORMATION
LFC Files

Responses Received From
Department of Health (DOH)
Health Policy Commission (HPC)
Public Education Department (PED)

SUMMARY

Synopsis of Bill

House Bill 271 requires that children under age 8 and pregnant women only receive influenza vaccine that contains no more than a trace of mercury. The bill allows for exemptions when, in the judgment of the health care provider, the vaccine is medically indicated and mercury-free or trace vaccine is unavailable. DOH can authorize an exemption from the provisions if necessary to ensure that an adequate supply of vaccine is available to protect the public's health. DOH is also directed to implement a plan to increase immunizations among school children and children in daycare.

FISCAL IMPLICATIONS

Although the bill does not contain an appropriation, DOH indicates an additional cost is associated with providing preservative-free vaccine. Preservative-free vaccine is packaged in single doses and costs $3.46 more per dose than multi-dose vaccines containing preservatives. DOH estimates that approximately 6,000 doses of preservative-containing influenza vaccine were given to high risk children and pregnant women in the 2005-2006 season. Vaccine prices have not been set for FY07; using current costs, the increased cost to purchase the same amount of preservative-free vaccine would be $20,760 (equivalent to approximately 10,000 doses of vaccine). The cost of increasing influenza vaccinations among schoolchildren and children attending day care will depend on the plan and has not yet been determined.

DOH does not explain the additional $202,410 it claims is needed for preservative-free vaccines in the ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT table above.

SIGNIFICANT ISSUES

DOH indicates childhood immunizations are one of the most cost-effective public health interventions, resulting in the almost entire elimination of polio, diphtheria, measles, mumps, rubella and tetanus among children in the United States.

Current guidelines for mercury exposure are based on methylmercury, contained in fish. Ethylmercury is contained in thimerosal, used as a preservative in vaccines to prevent bacterial/fungal growth. Ethylmercury has not been as well studied and specific exposure guidelines have not been developed. Although no specific safety problems have occurred, in 1999 the US Public Health Service and the American Academy of Pediatrics urged the removal of thimerosal from childhood vaccines to reduce the overall exposure of infants to mercury as a precautionary measure.

There has been significant media attention recently regarding these exposures that has increased the awareness and concerns of the public. Concerns have been raised about potential mercury exposures from vaccines containing thimerosal.

The conclusions of the Institute of Medicine (IOM) Report, Immunization Safety Review: Vaccines and Autism (May 2004) concluded that: thimerosal-containing vaccines are not associated with autism and that the hypotheses regarding a link between autism and thimerosal-containing vaccines lack supporting evidence and are only theoretical. (http://www.iom.edu/CMS/3793/4705/20155.aspx). In addition, the IOM report expressed concern that "Using an unsubstantiated hypothesis to question the safety of vaccination . . . could lead to widespread rejection of vaccines and inevitable increases in incidences of serious infectious diseases like measles, whooping cough, and Hib bacterial meningitis."

A few remaining vaccines using thimerosal as a preservative include some tetanus-diphtheria (for over age 6 years), injectable influenza vaccines for persons over the age of 3 years, and a special vaccine for travelers to prevent Japanese encephalitis. Since mid-2001, vaccines routinely recommended for infants in the US have been manufactured either without or with only trace amounts of thimerosal thus already providing a substantial reduction in the total mercury exposure from vaccines for children.

Seven states have enacted legislation that restricts thimerosal content in vaccines; four set an age limit of three years of age.

Many physicians and immunization advocates fear that passing this type of legislation may give the misleading message that vaccines containing thimerosal-based preservatives are not safe. This may result in people not getting influenza and other vaccines that could protect their health. Current influenza vaccines that are thimerosal-free cost more, which could reduce the number of vaccines that the state and private providers can buy and administer. Uncertainty regarding exceptions may cause medical or legal concerns, potentially resulting in lower immunization rates.

DOH cautions that *any barriers* that lead to a reduction in influenza immunization could lead to increased illness, hospitalization and death.

ADMINISTRATIVE IMPLICATIONS

PED indicates it would be required to collaborate with the DOH, but PED currently has a health services consultant that can fill this role.

RELATIONSHIP

House Joint Memorial 5 establishes a task force to determine other ways to reduce exposures to mercury in New Mexico.

TECHNICAL ISSUES

HPC suggests, for clarity, "or" could be changed to "and," and "persons" could be changed to "women" in subsection B of the bill to read as follows:

Children under the age of eight ~~or~~ and ~~persons~~ women who are known to be pregnant shall not receive any influenza vaccine containing more than trace amounts of mercury as defined by the United States food and drug administration unless, in the judgment of the health care provider, administering the vaccine is medically indicated and mercury free or trace vaccine is unavailable and the patient or guardian is notified that the vaccine to be administered contains mercury.

OTHER SUBSTANTIVE ISSUES

HPC research indicates the following:

Thimerosal Toxicity

According to the US Food & Drug Administration (FDA):

- Allergic responses to thimerosal are described in clinical literature, with these responses manifesting themselves primarily in the form of delayed-type local hypersensitivity reactions, including redness and swelling at the injection site. Such reactions are usually mild and last only a few days.
- At the initial National Vaccine Advisory Committee-sponsored meeting on thimerosal in 1999, concerns were expressed that infants may lack the ability to eliminate mercury. More recent NIAID-supported studies at the University of Rochester and National Naval Medical Center in Bethesda, MD examined levels of mercury in blood and other samples from infants who had received routine immunizations with thimerosal-containing vaccines.

- Blood levels of mercury did not exceed safety guidelines for methyl mercury for all infants in these studies. Further, mercury was cleared from the blood in infants exposed to thimerosal faster than would be predicted for methyl mercury; infants excreted significant amounts of mercury in stool after thimerosal exposure, thus removing mercury from their bodies.
- These results suggest that there are differences in the way that thimerosal and methyl mercury are distributed, metabolized, and excreted. Thimerosal appears to be removed from the blood and body more rapidly than methyl mercury. NIAID is sponsoring a follow-up study with larger numbers of infants in Buenos Aires where thimerosal-containing vaccines are still administered to children.

Should Children Receive Influenza Vaccine Containing Thimerosal?

According to the Centers for Disease Control and Prevention (CDC) there is no convincing evidence of harm caused by the small amount of thimerosal in vaccines, except for minor effects like swelling and redness at the injection site due to sensitivity to thimerosal. Further, since 1999, newly formulated thimerosal preservative-free childhood vaccines (Hepatitis B, Hib, and DTaP) have been licensed. With the newly formulated childhood vaccines, the maximum total exposure during the first six months of life will now be less than three micrograms of mercury. Based on guidelines established by the FDA, the Environmental Protection Agency (EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR), no child will receive excessive mercury from childhood vaccines regardless of whether or not their flu shot contains thimerosal as a preservative.

Recent research suggests that healthy children under the age of 2 are more likely than older children and as likely as people over the age of 65 to be hospitalized with flu complications. Therefore, vaccination with reduced or standard thimerosal-content flu vaccine is encouraged when feasible in children, including those that are 6-23 months of age.

Should Pregnant Women Receive Influenza Vaccine Containing Thimerosol?

According to the CDC, a study of influenza vaccination examining over 2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine. Case reports and limited studies indicate that pregnancy can increase the risk for serious medical complications of influenza. One study found that out of every 10,000 women in their third trimester of pregnancy during an average flu season, 25 will be hospitalized for flu related complications.

Additionally, the CDC states that influenza-associated excess deaths among pregnant women have been documented during influenza pandemics. Because pregnant women are at increased risk for influenza-related complications and because a substantial safety margin has been incorporated into the health guidance values for organic mercury exposure, the benefits of influenza vaccine with reduced or standard thimerosal content outweighs the theoretical risk, if any, of thimerosal.

KBC/nt