Approved: March 28, 2007
Date

MINUTES OF THE SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

The meeting was called to order by Chairman James Barnett at 1:30 P.M. on March 22, 2007 in Room 231-N of the Capitol.

All members were present.
Senator Jordan – Excused

Committee staff present:
Emalene Correll, Kansas Legislative Research Department
Terri Weber, Kansas Legislative Research Department
Nobuko Folmsbee, Office of Revisor of Statutes
Morgan Dreyer, Committee Secretary

Conferees appearing before the committee:
Senator Dennis Wilson
Michael Wasmer, DVM, Olathe
Dr. Jo-Ann Harris, Kansas Chapter, American Academy of Pediatrics
Dan Morin, Director of Government Affairs, Kansas Medical Society
Richard Morrissey, Deputy Director, Division of Health, Kansas Department of Health and Environment

Others attending:
See attached list.

Upon calling the meeting to order, Chairman Barnett asked that the Committee review the Minutes for March 21, 2007 for approval at the end of the meeting.

The Chair called upon Nobuko Folmsbee to read and explain **SB 1** for the Committee. A handout of the new bill draft was given to the Committee. A copy of the draft is (Attachment 1) attached hereto and incorporated into the Minutes as referenced.

Questions came from Senators Schmidt and Wagle regarding acknowledgment of a debate and changes/amendments to the bill.

The Chair announced that the next order of business was to open the hearing on **SB 1**.

**Hearing on SB 1 – An act concerning public health, relating to vaccinations**

A copy of the fiscal note for **SB 1** was available for the Committee to review. A copy of the fiscal note is (Attachment 2) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett called upon proponent conferee, Senator Dennis Wilson who stated that the bill now with changes only restricts the use of a small amount of preservatives in vaccines for children seven and under, and for those women who are pregnant. He is not asking for any removal of mercury/preservatives in any other vaccines, such as animal vaccines or vaccines for adult consumption. A copy of his testimony is (Attachment 3) attached hereto and incorporated into the Minutes as referenced.

Senator Hensley also stated a few words to the Committee as a proponent conferee of the bill. No written testimony was submitted to the Committee.

Comments came from Senator Haley regarding thanking the Senators for bringing this public health concern to the attention of the Committee, balance of supply and demand concerning vaccines, single vs. multi-vile.

The Chair called upon proponent conferee, Michael Wasmer, DVM, Olathe who stated that this bill strongly supports compliance with recommended childhood vaccine schedules. It allows for Kansans to be better-informed consumers, and aims to improve vaccination rates by enhancing public confidence in the safety of our current and future vaccine supply. A copy of his testimony is (Attachment 4) attached hereto and incorporated into the Minutes as referenced.

Questions came from Senators Haley and Wagle regarding efforts in Missouri concerning legislation like **SB 1**, influenza, vaccination information regarding Dr. Wasmer's children.

Chairman Barnett then called upon opponent conferee, Dr. Jo-Ann Harris, Kansas Chapter, American Academy of Pediatrics who stated that she strongly opposes the bill and considers it dangerous to the welfare of the citizens of our state. A copy of her testimony is (Attachment 5) attached hereto and incorporated into the Minutes as referenced.

Questions came from Senators Schmidt and Wagle regarding supply issues of thimerosal-free vaccines, age difference in 8 to 7 years old, direct contradictions to CDC, ACI, and FDA and best interest of minimal mercury.

The Chair called upon opponent conferee, Dan Morin, Director of Government Affairs, Kansas Medical Society who stated that the Kansas Medical Society believes **SB 1** is unnecessary, studies regarding the hypothetical dangers of thimerosal are highly questionable, and passing the bill will draw attention away from more beneficial discussions concerning diagnosis, treatment, and resources to assist families of those afflicted with autism spectrum disorders. A copy of his testimony is (Attachment 6) attached hereto and incorporated into the Minutes as referenced.

Chairman Barnett then called upon neutral conferee, Richard Morrissey, Deputy Director, Division of Health, Kansas Department of Health and Environment who stated that if more physicians stop providing immunizations, children requiring vaccinations will likely be referred to local health departments, adding additional steps to the immunization process, which in turn may affect immunization rates in Kansas. A copy of his testimony is (Attachment 7) attached hereto and incorporated into the Minutes as referenced.

Submitted testimony was available for the Committee to review from Mady Hornig, MD, Director of Translational Research, Jerome L and Dawn Greene Infectious Disease Laboratory. A copy of her testimony is (Attachment 8) attached hereto and incorporated into the Minutes as referenced.

Submitted testimony was available for the Committee to review from Boyd Haley, PhD, Professor of Chemistry, Department of Chemistry, University of Kentucky. A copy of his testimony is (Attachment 9) attached hereto and incorporated into the Minutes as referenced.

Submitted testimony was available for the Committee to review from Richard Deth, PhD, Professor of Pharmacology, Northeastern University. A copy of his testimony is (Attachment 10) attached hereto and incorporated into the Minutes as referenced.

Submitted testimony was available for the Committee to review from Jennifer Lowry, MD, Medical Director, Mid-America Poison Control, Med-America Pediatric Environment Health Specialty Unit, University of Kansas Medical Center. A copy of her testimony is (Attachment 11) attached hereto and incorporated into the Minutes as referenced.

Submitted testimony was available for the Committee to review from Ronald Phillips, Animal Health Institute. A copy of her testimony is (Attachment 12) attached hereto and incorporated into the Minutes as referenced.

With no time left, the Chair closed the hearing on **SB 1** and announced that the next order of business was for the approval of Minutes.

The motion was made by Senator Schmidt to approve the Minutes. It was seconded by Senator Journey and the motion carried.

**Adjournment**

As there was no time left, the meeting adjourned at 2:35 p.m.

MINUTES OF THE Senate Public Health and Welfare Committee at 1:30 P.M. on March 22, 2007 in Room 231-N of the Capitol.

There is no future meeting scheduled at this time.

Senate Public Health and Welfare Committee

Please Sign In March 22, 2007

| | |
|---|---|
| Michael Wasmer, DVM | Olathe, KS |
| Donald Bondank | Lenexa, KS |
| Pat Dubbert | Pharma |
| Nancy Zogleman | Pfizer |
| Aaron Cathis | KS. Livestock Assoc. |
| Michelle Peterson | Capitol Strategies |
| Will Deer | Federico Consulting |
| Barbara Belcher | Merck |
| Lon Lowrey | Novartis |
| Michael Ruiz | KDHE |
| Brenda Walker | KDHE |
| Jessica Wright | Gardner, KS - KUMC |
| Sarah Green | KHI News Service |
| Emily Geier | Hein Law Firm |
| Luke Thompson | KHPA |
| Susan Kang | ICDHE |
| Dick Morrissey | KDHE |
| Bill Sneed | Merck |
| | |
| Anthony Hensley | State Senator |

KDHE / Nobuko A# / Folmsbee

Senate Public Health and Welfare Committee
Attachment #1
March 22, 2007

Session of 2007

# SENATE BILL No. 1

By Senators Hensley and Wilson

11-15

AN ACT concerning public health, relating to vaccinations.

*Be it enacted by the Legislature of the State of Kansas:*

Section 1. (a) The legislature:

(1) Finds that immunizations are among the most effective preventative measures to preserve and protect public health;

(2) recognizes public concern regarding the use of the mercury-derived preservative thimerosal in vaccines;

~~(3)~~ finds that lingering public concerns about the safety of vaccines may be remedied by the removal of thimerosal from vaccines where such removal can be accomplished without injury to the public health or diminution in the available supply of vaccines;

(3) notes that many childhood vaccines given to children seven years of age or younger are thimerosal free in the United States;

further

(4)

~~(4)~~ endorses in the strongest possible terms the childhood and adult vaccination schedules promulgated by the advisory committee on immunization practices and the American academy of pediatrics; and

(5)

~~(5)~~ urges Kansans to comply with these recommendations.

(6)

(b) It is the intent of the legislature to minimize public fear and to increase public confidence in the safety of Kansas' vaccine supply ~~by explicitly limiting the mercury content of vaccines where substitutes are available~~.

Sec. 2. (a) On and after January 1, 2008, no person who is ~~eight~~ years of age or younger or who is knowingly pregnant shall be vaccinated in this state with a vaccine containing more than 0.5 micrograms of mercury per 0.5 milliliter dose.

seven

(.0001% concentration)

(b) The secretary of health and environment may exempt the use of a vaccine from this section if the secretary finds, and the governor concurs, that an actual or potential bioterrorist incident ~~or other~~ actual or potential public health emergency, including an epidemic or shortage of supply of a vaccine that would prevent children ~~eight~~ years of age or younger and knowingly pregnant women from receiving the needed vaccine, makes necessary the administration of a vaccine containing more than 0.5 micrograms of mercury per 0.5 milliliter dose. The exemption shall meet all of the following conditions:

, an

or other scenario

an outbreak,

seven

(.0001% concentration)

(1) It shall not be issued for more than 12 months.

(2) At the end of the effective period of the exemption, the secretary

may issue another exemption for up to 12 months for the same incident or public health emergency, if the secretary makes a determination that the exemption is necessary as set forth in this subsection and the governor concurs with the exemption.

(3) The secretary notifies the legislature and interested parties about the exemption pursuant to paragraphs (4), (5) ~~and (6)~~.

(4) Upon issuing an exemption, the secretary and the governor shall, within 48 hours, notify the legislature about the exemption and about the secretary's findings justifying the exemption's approval.

(5) ~~Upon request for an exemption, the secretary shall notify interested parties, who have expressed their interest to the secretary in writing, that an exemption request has been made.~~

~~(6)~~ Upon issuing an exemption, the secretary shall, within seven days, notify interested parties, who have expressed their interest to the secretary in writing, about the exemption and about the secretary's findings justifying the exemption approval.

(c) Should the secretary of health and environment pursuant to subsection (b) authorize the use of a vaccine containing more mercury than the level described in subsection (a), the vaccine may be administered to a child of ~~eight~~ years of age or younger upon the written and signed informed consent of the parent to the administration of such vaccine to the parent's child or to a knowingly pregnant woman who provides a written and signed informed consent to the administration of such vaccine. Such written informed consent, at a minimum, shall include a statement that the person signing the informed consent has been informed that the vaccine contains more than 0.5 micrograms of mercury per 0.5 milliliter dose; shall state the possible risks of receiving the vaccine containing the higher level of mercury; and shall state that the person signing the informed consent understands and ~~accepts the risks and consents to~~ the vaccination being given to the child or pregnant woman.

Sec. 3. On and after July 1, 2009, no vaccine administered in the state shall contain ~~any level of mercury~~.

Sec. 4. A person who knowingly administers a vaccine or other drug in violation of this act is guilty of a class C misdemeanor. ~~Such person may also be civilly liable under this act. Any person awarded damages in a civil action arising from a violation of the act shall be entitled to reimbursement for reasonable attorney fees and court costs.~~

Sec. 5. This act shall take effect and be in force from and after January 1, 2008, and its publication in the statute book.

and

seven

(.0001% concentration)

acknowledges the debate regarding the risks associated with

to any children seven years of age or younger

more than 0.5 micrograms of mercury (.0001 concentration) per 0.5 milliliter dose except as otherwise provided in subsection (b) of section 2, and amendments thereto.

KANSAS
DIVISION OF THE BUDGET

Kathleen Sebelius, Governor
Duane A. Goossen, Director
http://budget.ks.gov

February 9, 2007

The Honorable Jim Barnett, Chairperson
Senate Committee on Public Health and Welfare
Statehouse, Room 120-S
Topeka, Kansas 66612

Dear Senator Barnett:

SUBJECT: Fiscal Note for SB 1 by Senators Hensley and Wilson

In accordance with KSA 75-3715a, the following fiscal note concerning SB 1 is respectfully submitted to your committee.

SB 1 would limit the mercury content of vaccines where substitutes are available. Currently, traces of the mercury-derived preservative thimerosal, may be present in vaccines because of manufacturing processes. The bill would prohibit vaccination of any person who is eight years old or younger or of a person who is knowingly pregnant with a vaccine containing more than 0.5 micrograms of mercury per 0.5 milliliter dose on or after January 1, 2008. After July 1, 2009, no vaccine administered in the state could contain any level of mercury. The intent of the legislation is to minimize public fear and to increase public confidence in the safety of Kansas' vaccine supply. The bill would also establish that a person who knowingly administers a vaccine in violation of this act would be guilty of a class C misdemeanor and could also be civilly liable for the offense. An injured party could be awarded damages and reimbursement for reasonable attorney fees and court costs.

The Department of Health and Environment indicates that the implementation of SB 1 may create a shortage of influenza vaccine available to Kansans and medical providers. During a pandemic, it is expected that available vaccines would contain thimerosal which is used to avoid contamination when large quantities of the product are distributed. The Department indicates that the science of vaccine manufacturing would be able to allow for completely thimerosal-free or mercury-free vaccine by 2009. Trying to estimate a fiscal effect is difficult, as a determination would first have to be made as to whether there would need to be separate inventories for vaccines for children age eight and under and for those over the age of eight. Creating separate inventories would have planning and implementation costs; however, the Department is unable to estimate the fiscal effect of that process, if needed. Purchasing thimerosal-free influenza vaccine would increase costs by an estimated $49,197 to $89,079

900 S.W. Jackson Street, Room 504-N, Topeka, KS 66612 • (785) 296-2436 • Fax: (785) 296-0231
e-mail: duane.goossen@budget.ks.gov

Senate Public Health and Welfare Committee
Attachment #2
March 22, 2007

annually. The vaccine for Hepatitis A and B would cost an additional $154,012 each for a total increase of between $203,209 and $243,091 for public sector vaccine purchases. For information purposes, costs for vaccines are higher for private providers that are not eligible for the discounted prices available through the Vaccines for Children (VFC) program. Any fiscal effect resulting from the passage of this bill is not included in recommendations in *The FY 2008 Governor's Budget Report.*

Sincerely,

Duane A. Goossen
Director of the Budget

cc: Aaron Dunkel, Health & Environment

STATE OF KANSAS

DENNIS M. WILSON
SENATOR, 37TH DISTRICT
JOHNSON COUNTY
11925 GILLETTE
OVERLAND PARK, KANSAS 66213

DURING SESSION
STATE CAPITOL—141-E
TOPEKA, KANSAS 66612
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TOPEKA

SENATE CHAMBER

COMMITTEE ASSIGNMENTS
VICE-CHAIRMAN: TRANSPORTATION
MEMBER: FINANCIAL INSTITUTIONS AND INSURANCE
ELECTIONS AND LOCAL GOVERNMENT
JOINT COMMITTEE
ARTS AND CULTURE

E-mail: wilson@senate.state.ks.us

**Testimony in Support of Senate Bill 1**
**Presented to the Senate Public Health and Welfare Committee**
**By Senator Dennis Wilson**

March 22, 2007

Chairman Barnett and Members of the Committee:

Thank you for allowing me the opportunity to testify in support of Senate Bill 1.

I am aware that this subject matter has been before you the last couple of years, and that it raises much concern with those who are in the health care industry. Senator Hensley and myself are very much aware of the obstacles and concerns of this bill.

The bill before you has been drastically changed to alleviate the concerns of those in the health industry. The Fiscal Note on the bill would have to be changed to accommodate all of the possible amendments that will be presented to you by those who have worked on this bill, such as the Department of Health and Environment and several of our Kansas Citizens.

The bill now only restricts the use of a small amount of preservatives in vaccines for children seven and under, and for those women who are pregnant. We are not asking for any removal of mercury/preservatives in any other vaccines, such as animal vaccines or medicines for human consumption.

I have included an article from January 31 about one of the largest drug makers in the country who has voluntarily taken out preservatives to alleviate the fears of parents who are concerned about the possible link to autism and other possible illnesses.

The State of Kansas could take a lead role by passing Senate Bill 1 and support our children and citizens from the fear of Kansas vaccines. Knowing there will be much speculation and opposition for proof that preservatives are attributable to autism, I would ask you to consider this: If there is one chance in a million this could be happening, would you want to take that chance with your family? There are other alternatives that are safe and effective and would alleviate the fear and worries of the citizens we are elected to represent.

In conclusion, there is a book to support this position you could read, Evidence of Harm, which I hold a copy of.

Senate Public Health and Welfare comm.
Attachment #3
March 22, 2007

Thank you for reconsidering this important public policy change and I hope you will vote this bill out favorably after amending the bill with the changes we are suggesting.

I will stand for questions at the appropriate time and yield my time to those who have the technical knowledge to answer your questions.

Bloomberg.com

# Glaxo Changes Vaccine to Take Out a Controversial Preservative

By Catherine Larkin

Jan. 31 (Bloomberg) -- GlaxoSmithKline Plc, Europe's largest drugmaker, plans to begin selling a new formula of its Pediarix vaccine for children that doesn't contain preservatives that some parents fear may trigger autism.

The U.S. Food and Drug Administration approved Glaxo's request to change labeling for the new shot to say that it is free of preservatives, according to a letter posted today on the agency's Web site. Some parents and advocacy groups have raised concerns that thimerosal, a preservative containing mercury, may cause some children who are vaccinated to develop autism.

The FDA has been working with vaccine makers since at least 1999 to reduce or eliminate thimerosal, although health officials maintain that a link to autism hasn't been scientifically proven. Autism is an umbrella term for a range of developmental and communications disorders that affect as many as six of every 1,000 children in North America.

Glaxo removed trace amounts of the preservative in its new Pediarix formula and plans to phase in the new products ``in the near future,'' said Jennifer Armstrong, a spokeswoman for the London-based company.

``Our re-formulation has been made in response to public concern,'' Armstrong said today in a telephone interview. ``It's a very minor change.''

Pediarix is the only FDA-approved combination vaccine to treat five childhood diseases. The vaccine is given in three doses and protects infants from diphtheria, tetanus, polio, whooping cough and hepatitis B. About 21 million doses of Pediarix have been given in the U.S. since 2003.

Thimerosal has been used in drug products since the 1930s to prevent the growth of bacteria and fungi, according to the FDA's Web site.

To contact the reporter on this story: Catherine Larkin in Washington at clarkin4@bloomberg.net .

*Last Updated: January 31, 2007 16:43 EST*

March 22, 2007

**Testimony to the Senate Public Health and Welfare Committee in Support of Senate Bill No. 1**

Michael L. Wasmer, DVM, Diplomate ACVIM
14617 S. Garnett St.
Olathe, KS 66062
913-233-9101

My name is Mike Wasmer. I am a practicing veterinarian and board certified by the American College of Veterinary Internal Medicine in small animal internal medicine. I mention my credentials to make you aware that I am a public health professional with postgraduate education in immunology, toxicology and public health. I am also the father of two children, and I sincerely appreciate the opportunity to speak in strong support of Senate Bill 1.

Senate Bill 1 prohibits the use of mercury or mercury containing substances in vaccines administered to people seven years of age or younger, or knowingly pregnant women. It is this targeted population of people, i.e. children and developing fetuses, that are at highest risk of complications when exposed to mercury, which is a known neurotoxin.

Mercury, in the form of thimerosal, is present in some vaccines. Thimerosal is by weight approximately 50% ethyl mercury, and is added to some vaccines as a preservative because of its bactericidal properties. Preservatives are necessary to prevent bacterial contamination from repeat needle punctures when vaccines are manufactured for distribution in multi-dose vials. Preservatives are not necessary for vaccines manufactured for distribution in single dose vials.

In September 1999, the U.S. Public Health Service and the American Academy of Pediatrics issued a joint statement recommending that manufacturers "eliminate or reduce as expeditiously as possible the mercury content of their vaccines". [1] Many vaccine manufacturers have in fact eliminated the use of mercury-containing additives. However, included in my written testimony, I have provided a table from the U.S. Food and Drug Administration that lists 17 vaccines currently licensed in the United States that contain thimerosal.[2] Today, any of these mercury-containing products could be administered to the target population addressed by Senate Bill 1.

Opponents of Senate Bill 1 may point out that many vaccines on this list contain only trace amounts of mercury. In fact, Pediarix, a combination vaccine that protects against diphtheria, tetanus, polio, whooping cough and hepatitis B, contains less than 0.0125 micrograms of mercury, the least amount of mercury of

Senate Public Health and Welfare Committee
Attachment #4
March 22, 2007

all of the 17 vaccines. Yet in response to public concern GlaxoSmithKline, the manufacturer of Pediarix and a leader in the pharmaceutical industry, announced in January of this year that they have removed this trace amount of thimerosal. The reformulated Pediarix will be preservative free.[3] This move acknowledges that thimerosal is an unnecessary additive to vaccines. It also acknowledges that if given the choice, informed consumers would prefer a mercury-free vaccine.

In July 2001, when my daughter was 27 months old, she was diagnosed with autism. Although the definitive cause of autism has not been determined, there is clearly a strong genetic predisposition. However the cause of autism is not solely genetic, as evidenced by the epidemic increase in prevalence of the disorder in the last decade. Researchers believe that this trend supports the presence of an environmental trigger that precipitates the signs of autism in genetically predisposed individuals.

Most research in autism today is dedicated to isolating the specific genes associated with autism, and determining the source of the environmental trigger. The role of *en utero* and childhood exposure to mercury through vaccines is a topic of active research, but this issue has not been resolved.

In April 1999, when my daughter was less than 24 hours old, she received a hepatitis B vaccine that contained 12.5 micrograms of mercury. This is 1000 times the amount of mercury contained in the Pediarix vaccine prior to its recent reformulation. In the first 16 months of her life, she received a total of 125.0 micrograms of mercury in the form of thimerosal in vaccines.

My wife was 5 months pregnant with our son at the time my daughter was diagnosed with autism. Please consider the information that my wife and I had to weigh:

1. The odds of having a second child with autism are approximately 1 in 20 (compared to the current estimate of 1 in 150 in the general population).
2. Autism is 4 times more common in boys than in girls.
3. Mercury exposure is considered a possible trigger to developing autism in genetically predisposed individuals.
4. At the time of my son's birth in 2001, and today, mercury-containing preservatives remain in some vaccines administered to children and pregnant women.

Now, please consider these questions:

1. Given the same situation that my wife and I faced, would you vaccinate your son with a product that contains mercury?

2. If there were a history of autism in your family, would you vaccinate your child with a product that contains mercury?
3. If you or a loved one were pregnant, would you allow yourself or your loved one to be vaccinated with a product that contains mercury?
4. Do you know which vaccines currently contain thimerosal?
5. Do your constituents know which vaccines currently contain thimerosal?

If your answer to all of these questions is not unequivocally, "yes", then I urge you to support Senate Bill 1.

Senate Bill 1 strongly supports compliance with recommended childhood vaccine schedules. It allows for Kansans to be better-informed consumers, and aims to improve vaccination rates by enhancing public confidence in the safety of our current and future vaccine supply.

I appreciate the opportunity to testify today and I would be happy to stand for any questions.

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[1] Pediatrics Vol 104 No. 3 September 1999

[2] "Table 3: Thimerosal and Expanded List of Vaccines - (updated 11/16/2006)"; http://www.fda.gov/cber/vaccine/thimerosal.htm#tox

[3] http://www.bloomberg.com/apps/news?pid=20670001&refer=uk&sid=a5J5f8OKMj1g

| | | | |
|---|---|---|---|
| Influenza, live | FluMist[4] (MedImmune) | Free | Never contained Thimerosal |

Manufacturer abbreviations:
GSK = GlaxoSmithKline; WL = Wyeth Lederle; AP = Aventis Pasteur; M = Merck.
** Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of thimerosal contains 50 µg of Hg per 1 mL dose or 25 µg of Hg per 0.5 mL dose.
*** The term "trace" has been taken in this context to mean 1 microgram of mercury per dose or less.
1 HibTiITER was also manufactured in thimerosal-preservative containing multidose vials but these were no longer available after 2002.
2 Children 6 months old to less than 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL; children 3 years of age and older receive 0.5 mL.
3 A trace thimerosal containing formulation of Fluzone was approved on 9/14/02 and has been replaced with the formulation without thimerosal.
4 FluMist is not indicated for children less than 5 years of age.

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Table 2: Preservatives Used in U.S. Licensed Vaccines

| **Preservative** | **Vaccine Examples (Tradename; Manufacturer*)** |
|---|---|
| Thimerosal | DT<br>Td (several)<br>TT (several)<br>Influenza (several) |
| 2-phenoxyethanol and formaldehyde | IPV (IPOL; AP)<br>DTaP (Daptacel; AP) |
| Phenol | Typhoid Vi Polysaccharide (Typhim Vi; AP)<br>Pneumococcal Polysaccharide (Pneumovax 23; M) |
| Benzethonium chloride (Phemerol) | Anthrax (B) |
| 2-phenoxyethanol | DTaP (Infanrix; GSK)<br>Hepatitis A (Havrix; GSK)<br>Hepatitis A/Hepatitis B (Twinrix; GSK) |

*Manufacturer abbreviations:
GSK = Glaxo SmithKline; WL = Wyeth Lederle; AP = Aventis Pasteur; M = Merck; B=Bioport.

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Table 3: Thimerosal and Expanded List of Vaccines - *(updated 11/16/2006)*

| Thimerosal Content in Currently Manufactured U.S. Licensed Vaccines | | | | |
|---|---|---|---|---|
| **Vaccine** | **Trade Name** | **Manufacturer** | **Thimerosal Concentration[1]** | **Mercury** |
| Anthrax | Anthrax vaccine | BioPort Corporation | 0 | 0 |
| DTaP | Tripedia[2] | Aventis Pasteur, Inc | ≤ 0.00012% | ≤ 0.3 µg/0.5 mL dose |
| | Infanrix | GlaxoSmithKline | 0 | 0 |
| | Daptacel | Aventis Pasteur, Ltd | 0 | 0 |
| DTaP-HepB-IPV | Pediarix | GlaxoSmithKline | < 0.000005% | < 0.0125 µg/0.5 mL dose |
| DT | No Trade Name | Aventis Pasteur, Inc | < 0.00012% (single dose) | < 0.3 µg/0.5mL dose |
| | | Aventis Pasteur, Ltd[3] | 0.01% | 25 µg/0.5 mL dose |
| Td | No Trade Name | Mass Public Health | 0.0033% | 8.3 µg/0.5 mL dose |
| | Decavac | Aventis Pasteur Inc | ≤ 0.00012% | ≤ 0.3 µg mercury/0.5 ml dose |
| | No Trade Name | Aventis Pasteur, Ltd | 0 | 0 |
| Tdap | Adacel | Aventis Pasteur, Ltd | 0 | 0 |
| | Boostrix | GlaxoSmithKline | 0 | 0 |
| TT | No Trade Name | Aventis Pasteur Inc | 0.01% | 25 µg/0.5 mL dose |
| Hib | ActHIB/OmniHIB[4] | Aventis Pasteur, SA | 0 | 0 |
| | HibTITER | Wyeth-Lederle | 0 | 0 |
| | PedvaxHIB liquid | Merck | 0 | 0 |
| Hib/HepB | COMVAX[5] | Merck | 0 | 0 |
| Hepatitis B | Engerix-B<br>Pediatric/adolescent<br>Adult | GlaxoSmithKline | <br>< 0.0002%<br>< 0.0002% | <br>< 0.5 µg/0.5 mL dose<br><1µg/1 ml dose |
| | Recombivax HB<br>Pediatric/adolescent | Merck | <br>0 | <br>0 |



4-5

| | | | | |
|---|---|---|---|---|
| | Adult (adolescent)<br>Dialysis | | 0<br>0 | 0<br>0 |
| Hepatitis A | Havrix | GlaxoSmithKline | 0 | 0 |
| | Vaqta | Merck | 0 | 0 |
| HepA/HepB | Twinrix | GlaxoSmithKline | < 0.0002% | < 1 µg/1mL dose |
| IPV | IPOL | Aventis Pasteur, SA | 0 | 0 |
| | Poliovax | Aventis Pasteur, Ltd | 0 | 0 |
| Influenza | Fluzone[6] | Aventis Pasteur, Inc | 0.01% | 25 µg/0.5 mL dose |
| | Fluvirin | Evans | 0.01% | 25 µg/0.5 ml dose |
| | Fluzone (no thimerosal) | Aventis Pasteur, Inc | 0 | 0 |
| | Fluvirin (Preservative Free) | Evans | < 0.0004% | < 1 µg/0.5 mL dose |
| | Fluarix | GlaxoSmithKline | < 0.0005% | < 1.25 µg/0.5 mL dose |
| | FluLaval | ID Biomedical Corporation of Quebec | 0.01% | 25 µg/0.5 ml dose |
| Influenza, live | FluMist | MedImmune | 0 | 0 |
| Japanese Encephalitis[7] | JE-VAX | BIKEN | 0.007% | 35 µg/1.0mL dose<br>17.5 µg/0.5 mL dose |
| MMR | MMR-II | Merck | 0 | 0 |
| Meningococcal | Menomune A, C, AC and A/C/Y/W-135 | Aventis Pasteur, Inc | 0.01% (multidose)<br>0 (single dose) | 25 µg/0.5 dose<br>0 |
| | Menactra A, C, Y and W-135 | Aventis Pasteur, Inc | 0 | 0 |
| Pneumococcal | Prevnar (Pneumo Conjugate) | Lederle Laboratories | 0 | 0 |
| | Pneumovax 23 | Merck | 0 | 0 |
| Rabies | IMOVAX | Aventis Pasteur, SA | 0 | 0 |
| | Rabavert | Chiron Behring | 0 | 0 |



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| | | | | |
|---|---|---|---|---|
| Typhoid Fever | Typhim Vi | Aventis Pasteur, SA | 0 | 0 |
| | Typhoid Ty21a | Berna Biotech, Ltd | 0 | 0 |
| Varicella | Varivax | Merck | 0 | 0 |
| Yellow Fever | Y-F-Vax | Aventis Pasteur, Inc | 0 | 0 |

Table Footnotes

1. Thimerosal is approximately 50% mercury (Hg) by weight. A 0.01% solution (1 part per 10,000) of thimerosal contains 50 µg of Hg per 1 ml dose or 25 µg of Hg per 0.5 ml dose.
2. Aventis 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. This vaccine is not marketed in the US.
4. OmniHIB is manufactured by Aventis Pasteur but distributed by GlaxoSmithKline.
5. COMVAX is not licensed for use under 6 weeks of age because of decreased response to the Hib component.
6. Children under 3 years of age receive a half-dose of vaccine, i.e., 0.25 mL (12.5 µg mercury/dose.)
7. JE-VAX is manufactured by BIKEN and distributed by Aventis Pasteur. Children 1 to 3 years of age receive a half-dose of vaccine, i.e., 0.5 mL (17.5 µg mercury/dose).

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4/-7

**Addenda to Testimony to the Senate Public Health and Welfare Committee in Support of Senate Bill No. 1**

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**Addendum #1: Ethyl mercury versus methyl mercury**

Mercury in thimerosal is in the form of **ethyl** mercury, whereas the most commonly studied form of mercury exposure relates to **methyl** mercury as is found in some seafood.

The FDA has never required testing of thimerosal's safety or of its safe exposure levels for newborns and children. Recommendations regarding thimerosal have been based on a methyl mercury standard.

Opponents to Senate Bill 1 may refer to a 2002 study that demonstrated that mercury was cleared from the blood of infants exposed to thimerosal faster than would be predicted for methyl mercury.[1] The authors interpreted this observation to suggest that thimerosal is removed from the blood and body more rapidly than methyl mercury.

However in 2005, a study funded by the National Institutes of Health compared the effects of injected thimerosal versus orally administered methyl mercury in monkeys.[2] This study found that although total blood mercury declined more quickly in monkeys administered thimerosal versus methyl mercury, the amount of potentially more toxic inorganic mercury concentrations in the brains of thimerosal-exposed monkeys were twice that of methyl mercury exposed monkeys. The authors concluded that methyl mercury "is not a suitable reference for risk assessment from exposure to thimerosal-derived mercury."

With regard to the potential role of ethyl mercury exposure and developmental disorders in children, a 2001 Institute of Medicine (IOM) report found that there was not sufficient evidence to render an opinion, but noted the possibility of such a relationship and recommended that further studies be performed. A follow up report in 2004 abandoned this recommendation. The authors of the 2005 thimerosal study cited above commented on the 2004 IOM report:

> "This approach is difficult to understand, given our current limited knowledge of the toxicokinetics and developmental neurotoxicity of thimerosal, a compound that has been (and will continue to be) injected in millions of newborns and infants." (Burbacher, et al 2005)

**Addendum #2:** **Relative Costs of Vaccine Manufacturing versus Early Intensive Behavioral Therapy for Autism**

Manufacturing costs of single dose versus multi-dose vaccines[3]

| | 10 dose vial | 1 dose vial |
|---|---|---|
| **Total manufacturing cost** (US$) | 0.105 | 0.257 |
| **Total manufacturing cost for 10 doses** (US$) | 0.105 | 2.57 |

| | |
|---|---|
| Total cost savings of manufacturing 10 doses of a vaccine in one 10 dose vial versus 10 single dose vials: | $ 2.47 |
| Average annual cost of providing early intensive behavioral therapy to a child with autism to give that child a 50% chance of performing at a level equal to their peers: | $ 35,000.00 |

[1] Pichichero ME, et al. Lancet 360:1737-1741, 2002

[2] Burbacher, et. al. Environmental Health Perspectives Vol 113 No. 8 August 2005

[3] Drain et al, Bulletin of the World Health Organization 2003;81:726-731

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TESTIMONY ON SENATE BILL 1
Senate Public Health and Welfare Committee

Thank you Chairman Barnett and members of the committee.

My name is Jo-Ann Harris. I am a pediatrician specializing in infectious diseases at the University of Kansas Medical Center. I am here representing the Kansas Chapter of the American Academy of Pediatrics. The KAAP is a statewide organization representing over 95% of the practicing pediatricians in the state. The KAAP is providing testimony today in opposition to Senate Bill1.

Vaccinations are considered one of the most important public health initiatives in the history of mankind. Despite this there is a small minority of the public that are mistrustful of vaccines. Most of this is not based in scientific facts but on emotional factors that result in misconceptions and misinformation.

Thimerosal, a preservative found in a small number of vaccines, has been implicated by a few as causing autism and other illnesses in children. To date there has been no good evidence that associates thimerosal and autism or any illnesses. In 2004 the Institute of Medicine reviewed the available scientific evidence and did not find any causal relationship with thimerosal and autism. There have been several other large studies that have come to the same conclusion. This issue has been evaluated extensively and as a result based on the evidence the FDA has not removed these vaccines from the market. The CDC and the Advisory Committee on Immunization Practices continue to recommend these vaccines. Still the myth persists.

Passage of this bill has serious implications. If SB1 passes it would give the public the impression that these vaccines are unsafe despite the general scientific knowledge to the contrary. It would indicate to the public that vaccine safety oversight by the CDC and the FDA and ACIP is inadequate. . How then can they trust the safety of any vaccines? What will this do to vaccine rates?

SB1 would limit the states ability to quickly administer influenza vaccines in cases of epidemics. Ordering vaccines may take months of advanced notice. The process that the secretary must go through to get an exemption could result in a delay when vaccine shortages occur.

It is interesting that the bill allows exceptions to the restrictions such as epidemics. If these vaccines are truly unsafe why allow them at all? The answer is because they are not unsafe. Again, what type of mixed message are we sending to the public?

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What is the cost of this bill? First influenza vaccine without thimerosol costs 25-30% higher and results in wastage of vaccines since single dose units must be used. This would have an effect on the states Medicaid expenditures. Second if immunization rates decrease there could be increase in number of individuals suffering from the illnesses and health care costs would again be affected. Again all this is based on unproven claims.

Finally this legislation sets a bad precedent. Remember even without this bill no parent is forced to use a vaccine that has thimerosol in it as alternatives are available. Standard of care in medicine requires a physician to provide parents information about the advantages and disadvantages of various immunizations and answer questions prior to administration. The parent can then make an informed decision. This bill prevents that. The state takes over the decision and prevents an acceptable method of treatment. Will lawmakers do this with other medical treatments that are considered within the standard of care because small groups oppose them?

As a pediatrician one of the hardest things for me is to still feel the emotions for my patients but to remain objective in my decision making, because I know this is in the best interest of my patients. That is the difficult task in front of you. You can still feel the emotions but be objective in your decision making.

In summary we strongly oppose passage of SB1 and consider it dangerous to the welfare of the citizens of our state. Thank you.

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To: Senate Committee on Public Health and Welfare

From: Dan Morin
Director of Government Affairs

Date: March 22, 2007

Subject: SB 1;

The Kansas Medical Society appreciates the opportunity to submit the following comments on SB1 which would prohibit and criminalize the administration of any vaccines in the state of Kansas containing mercury (thimerosal) or mercury containing substance.

We oppose its passage because it restricts the use of FDA-approved vaccines for no scientifically sound reason. Such restrictions will put the health and well-being of Kansas residents at risk, particularly in the event of an influenza pandemic. Although thimerosal has never been shown to be harmful, it has been removed from or reduced to trace amounts for nearly 6 years in all vaccines routinely recommended for children 6 years of age and younger, with the exception of inactivated influenza vaccine. The reduction or elimination of thimerosal was, in principle, achievable because over time it was possible to replace multi-dose vials with single dose vials, which do not require a preservative. The current use of vaccines with no or only trace amounts of thimerosal represents a greater than 98 percent reduction from previous maximum exposure in young infants.

The Kansas Medical Society questions the very premise of the proposed legislation.

**Sec 1 (2), recognizes public concern regarding the use of the mercury derived preservative thimerosal in vaccines;**

**Sec 1 (4), finds that lingering public concerns about the safety of vaccines may be remedied by the further removal of thimerosal from vaccines where such removal can be accomplished without injury to the public health or diminution in the available supply of vaccines;**

**Sec 1 (5) (b), It is the intent of the legislature to minimize public fear and to increase public confidence in the safety of Kansas' vaccine supply.**

Much to the credit of recent immunization campaigns conducted by KDHE with the assistance of health care providers and other community health care groups; Kansas childhood immunization rates have risen for four consecutive years and have jumped to 12th in the nation from 43rd in 2004. Passage of SB1 could actually cause many Kansas parents to doubt the general safety of

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vaccines and to decline vaccinations for their children, a step backward in the efforts of Governor Sebelius' Blue Ribbon Immunization Task Force formed to encourage families to participate in vaccination and to reduce or eliminate preventable illness and deaths from communicable diseases.

There currently exists serious confusion and misinformation regarding vaccine safety. SB1 ignores the body of current scientific evidence on thimerosal-containing vaccines. While vaccines are essential for public health, no vaccine is 100% safe. There are rare, but sometimes serious, side effects associated with all vaccines.

In 2004, the Immunization Safety Review Committee of the Institute of Medicine (IOM) in the National Academies of Science concluded that there is no causal relationship between thimerosal-containing vaccines and autism. SB1 also ignores recommendations of the American Academy of Pediatrics and three national advisory committees that monitor vaccine safety issues:

- FDA's Vaccine and Related Biologic Products Advisory Committee, which recommends whether or not the FDA should license a particular vaccine;
- CDC's Advisory Committee on Immunization Practcies, which recommends whether a particular vaccine should be added or removed from the childhood immunization schedule;
- HHS's National Vaccine Advisory Committee, which recommends research priorities to enhance vaccine safety and effectiveness.

Nationwide proponents of anti-thimerosal vaccinations point to questionable studies showing a causal link between childhood vaccinations and autism. Former Kansas State Epidemiologist Gianfranco Pezzino M.D. testified before you last session on behalf of the Kansas Health Institute on SB 537. He cited the 2004 IOM study which referenced 7 studies reporting an association between thimerosal and autism.

"*Six of these studies (one of which unpublished) were conducted by the same two authors . . . who have for years attempted to demonstrate an association between mercury and autism. The seventh study was an unpublished, uncontrolled study. The committee found that the studies . . . had serious methodological flaws and their analytic methods were nontransparent, making their results uninterpretable.*"

- In the mid-70s pediatric neurologist in the United Kingdom, published a report suggesting that the pertussis (whooping cough) vaccine might cause brain damage in some children. The media publicized the story and parents - understandably - began to panic. The number of children being vaccinated against whooping cough fell from over 80% to below 50%. People forgot that whooping cough itself causes both brain damage and death. In Scotland alone about 100,000 children suffered from whooping cough between1977 and 1991 - and about 75 of them died. When the original research was investigated, it was found to have serious flaws. It was 20 years before vaccination levels returned to the levels before the scare.

- Ten of the original 13 authors of a controversial 1998 medical report which implied a link between autism and the combined MMR vaccine for measles, mumps, and rubella, have retracted the paper's interpretations.
- In the summer of 1999, there was a dramatic drop in the number of Kansas newborns receiving immunization against Hepatitis B after a recommendation to suspend vaccination due to thimerosal. A thimerosal-free vaccine was released four months later. Vaccinations rates for Hepatitis B still have not returned to 1999 levels.

The Centers for Disease Control (CDC) recommends that children over 6 months get vaccinated annually against the flu (influenza) with the inactivated flu shot. The benefits of the flu vaccination outweigh any theoretical risk from thimerosal. Around the country, at least nine children have died of flu this season, and six other child deaths have been tentatively linked to flu since Feb. 3, according to the CDC. Last year, 47 children under age 18 died from influenza. In 2003-2004, the worst recent flu season, 153 children died. In the United States alone, seasonal influenza lands about 200,000 people in the hospital, and costs more than $10 billion in lost productivity and direct medical expenses.

Pharmaceutical companies are continue to phase out the use of thimerosal and are moving toward new production methods that don't require such additives. But they're not at the point where enough vaccine can be mass-produced for flu as quickly as needed, so not everyone would get it. There exists currently a preservative-free influenza vaccine (with only trace amounts of thimerosal) available in single dose pre-filled shots should a patient remain concerned after appropriate discussions with a physician. This would not be the case should an influenza outbreak occur.

**Section 3 states, On and after July 1, 2009, no vaccine administered in the state shall contain any mercury or mercury containing substance as a preservative.**

As stated above, thimerosal-free vaccine can be packaged only in single-dose units. It is necessary to package vaccines in multi-dose vials to prepare for any future influenza pandemic. Kansas would be far short of the capacity needed to fill enough single dose vials for a majority of residents. Vaccines take months to make — current flu vaccine production must start in the early spring so vaccines can reach consumers by October and November. The exceptions allowed the Kansas Department of Health and Environment within SB1 to exempt vaccines containing mercury would cause unnecessary delays and be futile in the face of a serious influenza outbreak in Kansas. Experts predict that a nationwide pandemic it could be more deadly than the Spanish flu that killed more than 500,000 Americans -- and more than 20 million people worldwide -- in 1918. And, in an important difference from seasonal flu, recent avian flu discussions is that avian flu would spread faster, because its victims are contagious before they know they have it. The bill attempts to head off these problems by allowing an exemption in cases of seasonal flu shortages and for health emergencies such as a pandemic. But the ban becomes tighter in July 2009, with no allowance for even trace amounts of the substance and the exemption for shortages and pandemics is seemingly no longer allowed.

**Section 2 (b) states, the secretary of health and environment may exempt the use of vaccine from this section . . .**

The Kansas Medical Society believes SB1 is unnecessary, studies regarding the hypothetical dangers of thimerosal are highly questionable, and passing the bill will draw attention away from more beneficial discussions concerning diagnosis, treatment, and resources to assist families of those afflicted with autism spectrum disorders.

Thank you for your time and attention to our comments. I would be happy to respond to any questions.

# Q&A

# Thimerosal: What you should know

Volume 1 Spring 2006

Vaccine Education Center *at*
The Children's Hospital *of* Philadelphia

Some parents are concerned that thimerosal, a mercury-containing preservative contained in the influenza vaccine, causes autism. However, during the past few years, a series of biological and epidemiological studies have shown this concern to be unfounded. Here is a summary of the evidence showing that, while some things do cause autism, mercury in vaccines isn't one of them.

## *All mercury isn't the same: methylmercury vs. ethylmercury*

Mercury is a naturally occurring element found in the earth's crust, air, soil and water. Since the earth's formation, volcanic eruptions, weathering of rocks and burning of coal have caused mercury to be released into the environment. Once released, certain types of bacteria in the environment can change mercury to methylmercury. Methylmercury makes its way through the food chain in fish, animals and humans. At high levels, it can be toxic to people.

Thimerosal — a preservative still used in the influenza vaccine — contains a different form of mercury called ethylmercury. Studies comparing ethylmercury and methylmercury suggest that they are processed differently in the human body. Ethylmercury is broken down and excreted much more rapidly than methylmercury. Therefore, ethylmercury (the type of mercury in the influenza vaccine) is much less likely than methylmercury (the type of mercury in the environment) to accumulate in the body and cause harm.

"Scientific evidence clearly indicates that mercury in vaccines doesn't cause autism."

## *Evidence that mercury doesn't cause autism*

• In 1971, Iraq imported grain that had been fumigated with methylmercury. Farmers ate bread made from this grain. The result was one of the worst single-source mercury poisonings in history. Methylmercury in the grain caused the hospitalization of 6,500 Iraqis and killed 450. Pregnant women also ate the bread and delivered babies with epilepsy and mental retardation. But they didn't deliver babies with an increased risk of autism.

• Four large studies have now compared the risk of autism in children who received vaccines containing thimerosal to those who received vaccines without thimerosal. The studies were consistent, clear and reproducible — the incidence of autism was the same in both groups. Denmark, a country that abandoned thimerosal as a preservative in 1991, actually saw an increase in autism beginning several years later.

• Studies of the head size, speech patterns, vision, coordination and sensation of children poisoned by mercury show that the symptoms of mercury poisoning are clearly different from the symptoms of autism.

• Methylmercury is found in low levels in water, infant formula and breast milk. Although it is clear that large quantities of mercury can damage the nervous system, there is no evidence that the small quantities contained in water, infant formula and breast milk do. An infant who is exclusively breast-fed will ingest more than twice the quantity of mercury that was ever contained in vaccines and 15 times the quantity of mercury contained in the influenza vaccine.

6-5

more ▶

# Thimerosal: What you should know

## *What is known about the causes of autism?*

• First, like cystic fibrosis or sickle cell disease, autism clearly has a genetic basis. Researchers found that when one identical twin had autism, the chance that the other twin had autism was about 90 percent; for fraternal twins, the chance was less than 10 percent.

• Second, although autism clearly has a genetic basis, environmental factors can also cause the disease. For example, children whose mothers took thalidomide during pregnancy had birth defects, including malformed ears and shortened limbs. But they also had a significantly greater incidence of autism than babies born to mothers who never took thalidomide. Thalidomide clearly caused autism, but only if mothers took it early in pregnancy. If mothers took thalidomide in the second or third trimester of pregnancy, their babies weren't at increased risk of autism.

• The thalidomide experience showed that there was a vulnerable time early in pregnancy when a drug could possibly cause autism. Echoes of the thalidomide story are found in babies infected with rubella virus. Babies born to mothers who suffered rubella early in their pregnancies develop birth defects involving the eyes, ears, brain and heart. They also are at greater risk of developing autism; but, as with thalidomide, only if the baby is exposed to rubella early during pregnancy. Babies don't develop autism if they are infected with the virus soon after birth. Taken together, these findings suggest that a virus or a drug can cause autism, and that there is a vulnerable time early during pregnancy when the baby is at risk. However, during the second or third trimester of pregnancy, or after the child is born, the window for environmental factors causing autism has apparently closed.

• Women in the United States also occasionally received mercury when they were pregnant. It happened when doctors found that the mother's blood type was not compatible with their baby's blood type. To prevent this blood mismatch from hurting the baby, mothers were given RhoGam, a product that contained thimerosal as a preservative. However, consistent with the observation in Iraq, babies exposed to thimerosal in RhoGam did not have a greater risk for autism than babies whose mothers never received RhoGam. Although thalidomide and rubella virus can cause autism in pregnancy, scientific evidence clearly indicates that mercury doesn't.

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This information is provided by the Vaccine Education Center at The Children's Hospital of Philadelphia. The Center is an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from The Children's Hospital of Philadelphia. The Center does not receive support from pharmaceutical companies.

Some of this material was excerpted from the book, *Vaccines: What You Should Know*, co-authored by Paul A. Offit, M.D., and Louis M. Bell, M.D.

KANSAS

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Roderick L. Bremby, Secretary

DEPARTMENT OF HEALTH
AND ENVIRONMENT

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Division of Health

**Testimony on Senate Bill No.1**
**Regarding Vaccines Containing Mercury**
**to**
**Senate Public Health and Welfare Committee**

**Presented by**

**Richard Morrissey**
**Deputy Director, Division of Health**
**Kansas Department of Health and Environment**

**March 22, 2007**

Chairman Barnett and Members of the Committee, I am Richard Morrissey. I serve as Deputy Director of the Division of Health at the Kansas Department of Health and Environment. We are testifying on the bill with the proposed amendments. SB 1, with the proposed amendments, requires that after July 1, 2007, no child seven years of age or younger, or a pregnant woman, shall be vaccinated with a vaccine containing more than 0.5 micrograms of mercury per 0.5 milliliter dose. (For the purposes of this bill, we assume that the word "mercury" refers to thimerosal, a compound containing ethyl mercury and used as a preservative in vaccines.) SB1 further indicates that after July 1, 2008, no vaccine administered in the state shall contain any mercury. The bill makes an exemption to this law possible if approved by the Secretary of KDHE and the Governor in cases of public health need. As others will speak to the scientific aspects of this issue, my testimony today will be neutral and reflect only upon the operational aspects of the bill.

With rare exception, no commonly used childhood vaccines contain thimerosal above the amount noted in SB 1. There are essentially only two vaccines that still do. One is a combination vaccine against both hepatitis A and B (there are thimerosol-free forms of vaccines against only hepatitis A or B, but none in combination). The other is the influenza vaccine, and specifically only the vaccine found in multi-dose vials. (The reason for this is that in a single-use vial, the seal is broken once and the product used immediately. In a multi-dose vial, thimerosal is needed to prevent contamination of the vaccine by bacteria and fungi once the seal has been broken for the first time.) There is a preservative-free form of the flu vaccine with less thimerosal than mandated by SB 1 currently available. However, only about 34 million of the 110 million doses of injectable influenza vaccine that were produced for the 2006-2007 vaccination season were a thimerosal-free formulation. The limited amount of thimerosal-free vaccine might mean that not all those who need to be vaccinated could get the vaccine, especially in a more severe flu season or in the event that vaccine against a pandemic influenza

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was available in a multidose preparation. Increasing data has demonstrated that children are often "super spreaders" of influenza, making increasing levels of childhood immunization over that we currently achieve a key to protecting all. Case reports and limited studies indicate that pregnancy can increase the risk for serious medical complications of influenza.

We believe that while the exception process may seem cumbersome, we can work through the exemption provisions as needed to protect Kansans from outbreaks of disease, including but not limited to annual outbreaks of seasonal influenza. However, there are some potential concerns about how the bill may affect health care providers. We do not know the impact the bill might have on the ability of physicians and local health departments to acquire and pay for supplies of thimerosol-free vaccine given the external market forces in play, whether or not an exemption has been granted pursuant to the bill. We also cannot predict if the enforcement provisions within the bill will have the effect of promoting thimerosol-free vaccination within physician offices or result in more physicians declining to provide primary immunizations due to the additional regulation, time constraints from the consent procedure, or legal penalties. If more physicians stop providing immunizations, children requiring vaccinations will likely be referred to local health departments, adding additional steps to the immunization process, which in turn may affect immunization rates in Kansas.

Thank you for the opportunity to appear on this bill.

CONGRESSIONAL TESTIMONY

U.S. HOUSE OF REPRESENTATIVES
TESTIMONY FOR HEARING ON KANSAS SB. 1

submitted by:

Mady Hornig, MD
Director of Translational Research
Jerome L. and Dawn Greene Infectious Disease Laboratory

Associate Professor of Epidemiology
Mailman School of Public Health
Columbia University

Thank you for this opportunity to submit this testimony regarding potential hazards for human health from cumulative exposures to mercury-containing compounds. Exposure to mercury and other neurotoxic agents is now ubiquitous throughout the globe, and evidence is growing to suggest that a substantial sector of the US population may be at heightened risk for deleterious effects. The brains of fetuses and children are especially vulnerable due to their immaturity. The level that constitutes a significant risk remains undetermined. Our work has focused on the toxicity of the ethylmercury-containing vaccine preservative, thimerosal, in a genetically-focused animal model, and its implications for human disease. Our research addresses whether genes are important determinants of developmental outcomes following subtoxic mercury exposures akin to those previously found in most childhood immunizations, and still present in influenza and other vaccines. We found that in genetically-sensitive mice, thimerosal does indeed disrupt brain development and function. The meaning of these findings for humans remains to be determined, but it is clear from this work, and from related work in monkey models and in humans, that many more questions need to be addressed with proper research. The first paper was published on this animal model in the Nature Publishing Group journal, *Molecular Psychiatry* (Hornig M, Chian D, Lipkin WI. Neurotoxic effects of postnatal thimerosal are mouse strain dependent. *Mol Psychiatry* 2004;*9*:833-845).

The premise of our research is that if mercury in vaccines creates risk for neurodevelopmental disorders such as autism, genetic differences are likely to contribute to that risk. We built upon an extensive, existing literature on toxicity of other forms of mercury in inbred mouse strains that affirmed the importance of specific genes controlling immune responses (major histocompatibility complex, or MHC) in determining mercury-induced autoimmune outcomes in mice. ~~These~~ Earlier studies, however, did not use the form of mercury present in vaccines, known as thimerosal, and did not consider whether intramuscular, repetitive

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administration during early postnatal development, when the brain and immune systems are still maturing, might intensify toxicity. Based on reports of immune disturbances and family history of autoimmune disease in a subset of children with autism, we hypothesized that immune response genes linked to mercury immunotoxicity in mice would predict damage following low-dose, vaccine-based mercury in our mouse model.

Our predictions were confirmed. Using thimerosal dosages and timing that approximated the childhood immunization schedule, our model of postnatal thimerosal neurotoxicity demonstrated that the genes in mice that predict mercury-related immunotoxicity also predicted neurodevelopmental damage. Features reminiscent of those observed in autism occurred in the mice of the genetically sensitive strain, including: generalized behavioral impoverishment and abnormal reaction to novel environments; enlargement of the hippocampus, a region of the brain involved in learning and memory; correlation of hippocampal enlargement with abnormalities in exploration and anxiety; increased packing density of neurons in hippocampus; and disturbances in glutamate receptors and transporters. Only mice carrying the susceptibility gene ($H\text{-}2^{s}$) showed these autism-like effects (SJL/J mice). Two mouse strains with different versions of this gene (C57BL6/J mice, $H\text{-}2^{b}$; BALB/cJ mice, $H\text{-}2^{d}$) did not demonstrate adverse consequences following thimerosal exposure.

These animal model studies do not provide conclusive evidence regarding a link between mercury exposure and human autism. Nonetheless, the finding that a specific genetic constraint profoundly alters the brains and behavior of thimerosal-exposed mice confirms the biological plausibility of thimerosal neurotoxicity, provides critical guidance for the interpretation of existing epidemiologic investigations into the potential association of thimerosal with neurodevelopmental disorders, and suggests important new avenues for future research. Our work implies that if genetic factors are operative in mediating a link between thimerosal and autism in humans, then studies, even in large human populations, that fail to consider genetic susceptibility factors will be compromised in their ability to detect a statistically significant effect even if one exists.

Recent findings, presented at scientific meetings but as yet unpublished, suggest that thimerosal neurotoxicity in susceptible mice involves the generation of autoantibodies targeting brain components. This autoimmune response appears to persist long after the presence of mercury can no longer be detected. If confirmed, these findings will enable us to develop a human diagnostic test to determine whether some individuals with autism have similar autoantibodies present in their peripheral blood. Such work would not only bring us a step closer to identifying the genes associated with thimerosal neurotoxicity in humans, facilitating prevention programs, it would also validate the utility of this animal model for the development of safe and effective modes of intervention.

It is highly likely that the neurotoxic effects of cumulative mercury burden, including exposure to other sources or forms of mercury (thimerosal in products other than vaccines; methylmercury in contaminated fish; atmospheric exposures), follow similar patterns of genetic restriction; it is also likely that similar genetic factors influence the neurotoxicity observed following exposure to xenobiotics other than mercury (e.g., PCBs, the PBDEs used as flame retardants in computers, and infectious agents). Age and developmental status at the time of exposure, nutritional factors, and gender are also known to influence outcomes. We have limited ability to explain the interplay of such factors in humans; consider the example of the disparate cognitive outcomes reported in children in the Faroe Islands and the Seychelles after similar prenatal methylmercury exposures. The reasons for this divergence remain unclear. The design of future epidemiologic studies must take into account the possibility of multiple xenobiotic exposures as well as the influence of factors that modulate risk. Our studies have important implications for understanding the role of gene-environment interactions in the pathogenesis of autism and related neurodevelopmental disorders.

In October 2004, at a Congressional Hearing on this matter – the same day the Chiron vaccine contamination story broke (given that the Chiron vaccine was preserved with mercury, the contamination of this vaccine stock in October 2004 seriously questioned the effectiveness of thimerosal as an antimicrobial agent) – US Rep. Ralph Regula chastised the FDA for not mandating compliance among vaccine manufacturers with guidelines issued by his Committee in 2001. The 2001 directives had stated that vaccine manufacturers should voluntarily begin the transition to manufacturing facilities capable of producing mercury-free, sterile, safe, and effective vaccines using the latest technologies. It is simple and expedient for vaccine manufacturers to produce sterile syringes pre-filled with single doses of mercury-free vaccine.

Even today, in 2007, manufacturers are still not in full compliance with these guidelines. Their decision to not comply with governmental guidelines should not be based on their companies' profit margins, but rather on a margin of unquestionable safety for our nation's children. The accelerating accumulation of these toxins throughout the US and the world, raising the background levels of exposure in our entire population, places the intentional introduction of any additional such exposures of mercury to the developing, vulnerable nervous system in the realm of unacceptable risk. Rather than allowing such a risk to be taken in the name of profit, proactive, and compassionate lawmakers should place a premium on research into the role of environmental triggers, and how these may interact with other susceptibility factors in the development of serious childhood neuropsychiatric disorders. Withdrawal of mercury from vaccines is an action that will strengthen public confidence in the safety of our nation's immunization programs.

# Expert Report of Boyd E. Haley, Ph.D.

Date: 6 April 2006

**To Whom it May Concern:** My name is Boyd E. Haley, Ph.D. and I am Professor of Chemistry in the Department of Chemistry at the University of Kentucky. Throughout my career I have studied the effects of numerous compounds on the activity of enzymes, proteins and cellular function. In the past 14 years I have concentrated my research on the effects of mercury toxicity on human health. Below is my opinion on the relationship of mercury exposures and the onset of neurodevelopmental disorders. Specifically, I address the possibility that exposures to thimerosal delivered by infant vaccinations and $Rh_0$ (D) Immune Globulin injections could be causal for neurological injury. In papers of analysis various infant vaccines and Rhogam products supplied to me by others I have read that the mercury concentrations vary between 22.4 to 60 micrograms mercury per ml. At 25 and 50 micrograms per ml the mercury concentration in the $Rh_0$ (D) would be 125,000 and 250,000 nanomolar, respectively. This is important because some of the very recent damage observed by thimerosal in test systems for neurological toxicology, and reported below, is observed at very low nanomolar levels.

What many research groups have observed is that mercury and organic mercury compounds rapidly and specifically inhibit the activity of certain "thiol-sensitive" enzymes. Most prominent among these is the protein tubulin that polymerizes to form microtubulin, and serves as an important cytoskeletal factor for both the structure of nerve axons *(Pendergrass, J. C., Haley, B.E., Vimy, M. J., Winfield, S.A. and Lorscheider, F.L. Mercury Vapor Inhalation Inhibits Binding of GTP to Tubulin in Rat Brain: Similarity to a Molecular Lesion in Alzheimer's Disease Brain. Neurotoxicology 18(2), 315-324, 1997)*, cell membranes and as a scaffolding for the mitotic spindle involved in cell division. There is no doubt that exposure to mercury immediately and effectively disrupts microtubulin structures and, in the case of neurons, destroys normal neuronal function. Neuronal death is effected by low nanomolar levels of thimerosal in culture (*Haley, B. Mercury Toxicity: Genetic Susceptibility and Synergistic Effects. Medical Veratis 2 (2005) 1-8.*) and macrophage phagocytosis, the first step in the innate immune system is inhibited by 1 to 5 nanomolar thimerosal. Observations such as these have lead to mercury compounds being classified as severe neurotoxins and immune system suppressors.

In the case of the mitotic spindle a similar disruption of microtubulin prevents normal cell division and this is required for immune T and B cells to divide to support an immune response. This is why both inorganic mercury and organic mercury are classified as severe immune system suppressors. One of the most prominent of organic mercury exposures to humans comes from the compound thiomerosal, which breaks down rapidly in the body to release ethyl-mercury, a compound of known extreme

toxicity. Thimerosal has been used as a preservative in various Rhogam injections since the product was first introduced.

I recently read a research paper entitled "Porphyrinuria in Childhood Autism Disorder: Implications for Environmental Toxicity" by Nataf et al. accepted for publication in Toxicology and Applied Pharmacology on 5/04/06. The manuscript found 53% of the autistics they studied in a large clinic in Paris, France had aberrant porphyrin profiles that were symptomatic of mercury toxicity. Treating the children with DMSA, a mercury chelator, caused this physiological abnormality to return to near normal eliminating genetics as the cause of the abnormal prophyrin problem and strongly indicating mercury as being causal. A major exposure to mercury in small children, other than diet, would be the thimerosal received while in utero in the form of Rhogam shots to the mother and childhood vaccines. This report follows on another recent report from the University of California at Davis which describe the exceptionally potent toxicity of thimerosal towards dendritic cells, with lethality occurring at the low nanomolar levels.

It is important to acknowledge the importance of mercury inhibition of porphyrin synthesis profiles as the final product of this biochemical pathway is the synthesis of the "heme" molecule that has additional important functions in the body. First, it is the prosthetic group that must be attached to globlin protein to form "hemoglobin", the oxygen carrying protein of the body. Without "heme" inadequate oxygen delivery is possible. Most important, this "heme" is also a prosthetic group for the class of detoxifying enzymes called P450. Without adequate amounts of heme the body would have greatly reduced ability to detox from many different toxic exposures. Finally, the "heme" protein is critical for the major energy producing pathway in the body, and that is the ETS (electron transport system) of the mitochondria. Without adequate heme certain cells would not be able to produce the energy needed for many body functions, including the energy required for excreting mercury and other toxins. This is most likely one of the major reasons that mercury enhances its own retention in susceptible individuals.

At this date I have not read any first hand information as to the possible safety studies done by manufacturers making the thimerosal containing vaccines or Rhogam shots. For my evaluation of the potential toxicity of these materials I have used the material that accompanies the vaccine and Rhogam products stating the thimerosal (ethylmercury) levels.

Testing has shown that ethyl-mercury is very toxic to microtubulin formation and subsequently and can suppress the immune system. For example, thimerosal at 1.0 nanomolar concentration inhibits phagocytosis, an essential step in the innate immune response (*Rampersad et al., Transfusion 45(3):384-93,2005)*, similar to the concentration effects seen in the UC-Davis study on mouse dendritic cells. It most likely does this by disrupting the cytoskeletal structure of the macrophage thereby

preventing phagocytosis. Therefore, an infant exposed to the ethylmercury from one vaccination or Rhogam shot while *in utero* would likely have their innate immune response significantly inhibited for an extended period of time.

I have reviewed the literature on thimerosal and have found numerous supporting references on its toxicity and many reports expressing the opinion that thimerosal is to toxic to be used in medicinals. A 1977 report (*Organ Mercury Levels in Infants with Omophaloceles Treated with Thimerosal. Fagan et al. Archives of Disease in Childhood 52, 962-64, 1977)* described the death of 10 of 13 babies with infected umbilical cords that were treated with thimerosal topologically. This study lead to many medicinals, such as mercurochrome/merthiolate which contained thimerosal, to be removed from the over-the-counter market by the FDA in 1978 because they were considered too toxic. Thimerosal was also been removed from optical solutions for the same reason.

However, thimerosal in merthiolate and similar topical ointments was used widely on adolescents for many years with out extensively reported negative problems. This strongly indicates that thimerosal exposures to infants early after birth, or *in utero,* is much more toxic than it is to older children. This is supported by the observation that the individuals most adversely affected in the Minamata Bay disaster (where the exposure was from methyl-mercury from the diet) were the infants exposed *in utero.* Also, pregnant mothers seemed to be protected by the higher absorbance of the organic-mercurial of the fetus. (*Minamata Disease. Study Group of Minamata Disease, Kumamoto University, Japan, 1968; H. G. Matsumoto, T. Koya and T. Takeuchi J. Neuropath. Exp. Neurol. 24, 563, 1965*) It is also well known that the mercury levels in cord blood is, on average, 1.7 times higher than that found in the mother's blood. (*Drasch, G., Schupp, I., Hofl, H., Reinke, R., Roider, G.: Mercury burden of human fetal and infant tissues. Eur. J. Pediatr. 153, 607-610 (1994) and G. Birke et al. Svenska Lakardidn 64, 3638, 1968.*) This supports the contention that exposure of the mother to mercury greatly increases the risk to any child she is carrying.

Consider, according to the EPA a safe level of exposure to oral mercury from a fish/whale diet would be 0.1mcg/kg body weight. This means that for a shot delivering 12.5 mcg of mercury the person would have to weigh 275 pounds for the exposure not to exceed the EPA standard. Few mothers make this weight limit. Quoting from the *NSF Summer Environmental Study, Indices Group Report on Mercury, 1970* "In one brief and ominous report, mercury levels were measured in the blood of 5, randomly chosen, pairs of mother and child at the birth of the child (66,72). The average mercury concentration in the blood cells of the newborn child was found to be 28% above that of the mothers. If the data for the children are plotted vs those for the mother (11), a relationship is obtained suggesting that both the relative and absolute accumulation of mercury from the mother-to-be into the human fetus may increase hazardously at higher mercury concentrations." (Referencing *as article 66: G. Birke, A.G. Johnels, L.o. Plantin, B. Sjostran and T. Westermark. Svenskea Lakardindn 64, 3628, 1968.; as*

*article 72: S. Tejning Report No. 68, 02 20, Dept. Occup. Med., Univ. Hosp. Lund, Sweden, 1968; as article 11: G. Lofroth. Ecological Res. Com. Of the Swedish Nat. Sci. Res. Council, Bull. No. 4, 1969.)*

Therefore, it has been know for about 3 decades that mercury concentrated in the fetal blood from the mother and that infants (or fetuses) were especially susceptible to mercury and organic mercury toxicity. This should have obviated any use of thimerosal in injectables as applying it topologically or exposure in the diet caused severe medical problems. It has also been recommended by many countries to practice medicine/dentistry that prevents any exposure of children or women of childbearing age to mercury due to the generally recognized increased toxicity of children and infants *in utero* to mercury.

Studies, now over 30 years old, (*Gasset et al,. Tetratogenicities of Opthalmic Drug, Arch. Opthalomology 93, 52-55, 1975.*) using radioactive mercury in thimerosal demonstrated that mercury was over 75% cleared from the blood in 6 hours and, at the same time, became elevated in the brain, liver and kidney of the test animals. This reports confirms that measuring mercury blood levels is an invalid method for determining mercury exposures. Additionally, since mercury is cleared from the blood into the urine then urine is also invalid. This is generally an accepted fact by those educated in mercury toxicity.

Based on the huge preponderance of medical and scientific literature on thimerosal showing that it is extremely toxic to humans, fetuses and infants in particular, one has to wonder why safety studies were not done to demonstrate safety in fetuses and infants or pregnant mothers. I have been unable to find any biological study on thimerosal where is has not been found to be severely toxic to the system being studied. Also, within the human population there appears, in my opinion, a subset of the population that is more susceptible to mercury toxicity than the bulk of the population. This is supported by the publication where it is demonstrated that some children do not excrete mercury as effectively as others. (*Holmes, A.S., Blaxill, M.F. and Haley, B. Reduced Levels of Mercury in First Baby Haircuts of Autistic Children. International J. of Toxicology, 22:1-9, 2003 and Lin-Wen Hu, J. Bernard and Che: Neutron Activation analysis of Hair samples for the Identification of Autism. Transactions of the Amercan Nuclear Society, v89, November 16-20, 2003*). Such susceptible individuals, such as the aged, are much more likely to be effected by what would be considered low-level exposures that would cause neurological illnesses or, more likely, exacerbate any predisposed neurological problems they may have. Therefore, infants exposed to ethylmercury from thimeroal *in utero* would be much more likely to develop a neurological problem than non-exposed infants.

In support of the causation of thimerosal in neurological disorders is the study that demonstrated that a subset population of mice exhibit neurological and immune affected biochemistry and behavior after exposures equal to that received by infants

(*Hornig M, Chian D, Lipkin WI. Neurotoxic Effects of Postnatal Thimerosal are Mouse Strain Dependent. Mol Psychiatry. 2004 Sep;9(9):833-45.*)

The risk of autism would be greater if the infant *in utero* were also genetically less capable of excreting mercury as many appear to be. Research has shown that some neurologically impaired children contain much lower concentrations of the natural compound (reduced glutathione) that is absolutely needed to effectively excrete mercury from the human body. Further, the recent research from Paris, France that has been recently accepted for publication (*Robert Nataf et al. Porphyrinuria in Childhood Autistic Disorder: Evidence for Environmental Toxicity, Toxicology and Applied Pharmacology, in press*) found that 53% of autistic children had urine porphyrin profiles indicative of mercury toxicity. The results of the French groups are consistent with other reports that show abnormal porphyrins profiles with mercury exposure (*James Wood, et al. The Association between Genetic Polymorphisms of Coproporphyrinogen Oxidase and an Atypical Porphyrinogenic Response to Mercury Exposure in Humans. Toxicology and Applied Pharmacology 206, 113-120, 2005).* Also, the results of this paper state "This finding represents the first report of a polymorphism in a human gene that modifies the effect of Hg on a biological process." This human gene, the CPOX gene, identifies the genetic etiology of an atypical porphyrinogenic response seen among 15% of the Hg exposed subjects. This fits in well with the reports that some children are very susceptible to mercury exposure and the publications by others that low glutathione levels render them susceptible to mercury toxicity (*James, S. J., P. Cutler, S. Myelnyk, S. Jernigan, L. Janak, D. W. Gaylor, and J. A. Neubrander. 2004. Metabolic biomarkers of increased oxidative stress and impaired methylation capacity in children with autism. Am. J. Clin. Nutr. 80:1611-1617.*)

Since treatment of the autistic children in the French report with a mercury chelator (DMSA) brought the porphyrin profiles back towards normal profiles it can be assumed that many of these children were still suffering from the toxic effects of mercury. Based on the age of these autistic children, and their lack of known mercury exposures, it is rational to believe that their mercury exposures came from early vaccines or Rhogam shots given to their mothers while they were *in utero* or nursing. It is well proven that such injections expose the children and mothers to levels of mercury considerably above the EPA recommended safe level. For example, to be able to meet the EPA safe level from a single vaccination (12.5 micrograms of mercury) the recipient would have to weigh 275 pounds, a level not likely reached by any infant or mothers.

Based on the above it is my strong belief that the cause of neurodevelopmental disorders in infants is most likely due to the well-documented bolus exposure to an organic-mercury compound such as thimerosal delivered through a Rhogam shot. Most importantly, the younger the fetus or infant the more significant the damage they are likely to incur if exposed to mercury.

I have received no compensation for my time in this matter or in preparation of this report.

_____

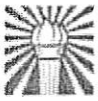
Boyd E. Haley, Ph.D.



9-6

**Morgan Dreyer - Written testimony in SUPPORT of Senate Bill 1 for the hearing on March 22**

**From:**
**To:**
**Date:** 3/20/2007 9:00 AM
**Subject:** Written testimony in SUPPORT of Senate Bill 1 for the hearing on March 22



Northeastern
UNIVERSITY
BOUVÉ COLLEGE OF HEALTH SCIENCES

March 19, 2007

Distinguished Senators:

The incidence of autism has risen by about forty-fold in the past twenty years, and there are strong indications that this increase reflects the neurotoxic influence of vaccine-derived ethylmercury on a genetically vulnerable subpopulation of infants and children. However, this pending legislation calling for the removal of thimerosal from vaccines is not a test of the mercury/autism hypothesis, rather it is about using common sense and requiring that drug companies provide the safest possible vaccine products in the State of Kansas.

It is well-known that thimerosal and other forms of mercury exert their toxic effects on pathways of sulfur metabolism. Indeed, the term "mercaptan" is a synonym for sulfur compounds, because their ability to capture mercury has been recognized for centuries. Clearance of mercury and other heavy metals from the body depends upon have enough of these sulfur-containing thiol compounds, including the amino acid cysteine and the anti-oxidant glutathione. Clinical studies, carried out by Dr. Jill James at Childrens Hospital in Little Rock, clearly show that levels of these protective sulfur compounds are markedly reduced in autistic children, in association with the presence of oxidative stress. Such lower levels are consistent with a restricted capacity to excrete mercury compounds, including the ethylmercury from thimerosal, as documented in other studies. Thus autistic children represent a vulnerable subpopulation with a higher sensitivity to heavy metal exposure. However, when mercury exerts such remarkable toxic effects in the most vulnerable among us, you can be assured that the entire population is experiencing some type of insult from it as well. Mercury exposure is a concern for everyone, and legislation to ban it from vaccines will benefit everyone in Kansas.

At Northeastern University, I have been investigating the molecular origins of neurological disorders including autism, ADHD and schizophrenia. About seven years ago we discovered that the neurotransmitter dopamine uses a process called methylation to regulate the firing frequency of nerves and this process plays a central role in attention, by synchronizing the activity of brain regions so they can effectively work together. Whenever oxidative stress is present, this methylation activity is inhibited and attention is impaired. It is likely that the large rise in ADHD is also attributable to impaired methylation.

Recent studies show that methylation activity in the human brain is much more sensitive to oxidative stress than is the case for other species. No wonder that oxidative stress has not only been linked to autism and ADHD, but also to Alzheimer's disease, Parkinson's disease and even schizophrenia. The reason for the higher sensitivity in humans is because nature has used oxidative stress as a tool to force cells to evolve and develop, and no matter whether you believe in divine or natural selection, the human brain is clearly the most highly developed example. Thus bringing mercury into the human body and letting it slip into the brain, where it stays for years, is an obviously foolish idea, unless you want to cause neurological illnesses.

We are now starting to understand the molecular origins of autism, and this knowledge makes it painfully obvious that we need to take action to eliminate thimerosal from vaccines. However, even if we didn't have these new metabolic and clinical results, we could still reach the same conclusion by using basic common sense. The CDC released their list of the most hazardous substances to human health, and mercury was #3, right after arsenic and lead. Just like arsenic, mercury is a

Senate Public Health and Welfare Committee
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poison, and there is no justification for injecting it into anyone, especially into infants and developing children.

Why are state legislatures around the country requiring removal of thimerosal from vaccines? Isn't this a role for the federal government? The answer is, of course, that federal agencies such as the FDA and CDC were asleep at the switch in recognizing the potential problem of mercury in vaccines. By pretending that it is not a problem, they are attempting to avoid responsibility, but more importantly they are extending the risk by not coming to grips with the problem. As a result, individual states like Kansas must take the initiative to protect the health of their citizens. I strongly urge your active support for this measure.

Thank you for this opportunity to provide testimony on this critical matter.

Sincerely,
Richard C. Deth, Ph.D.

Professor of Pharmacology
Northeastern University
360 Huntington Avenue
Boston, Massachusetts

10-2

March 21, 2007

Senator Jim Barnett
Chair, Public Health and Welfare Committee
State Capital Building, 120S
Topeka, Kansas 66612-1504

Dear Senator Barnett,

I am writing this in opposition of Senate Bill 1 that would allow a person who knowingly administers a vaccine or other drug in violation containing thimerosal to be guilty of a class C misdemeanor and be civilly liable under this act.

I am a trained pediatrician and completed fellowship training in clinical pharmacology and medical toxicology. Currently, I serve as the Medical Director to the Mid-America Poison Control Center (MAPCC) at the University of Kansas Hospital. We are Kansas' only poison control center and serve the entire state for poison exposures. In addition, I am the Medical Director to the Mid-America Pediatric Environmental Health Specialty Unit (MAPEHSU) at the University of Kansas Medical Center.

As part of its ongoing cooperative agreements with the Agency for Substances and Disease Registry (ATSDR) and the U.S. Environmental Protection Agency (EPA), the Association of Occupational and Environmental Clinics (AOEC) has established a network of Pediatric Environmental Health Specialty Units (PEHSUs). The PEHSU's have been developed to provide education and consultation for health professionals, public health professionals and others about the topic of children's environmental health. Services are often initiated regionally or can be coordinated across the network. The Mid-America Pediatric Environmental Health Specialty Unit (MAPEHSU) provides expert clinical, consultative, educational, and referral services to pediatric health professionals, parents, government agencies, and the general public in US EPA Region 7 (Iowa, Kansas, Missouri, and Nebraska).

I believe myself to be an expert in medical toxicology, environmental toxicology and the effects of poisons in all people, especially children. In addition, I believe myself to be a scientist that reviews medical literature with good judgment and makes appropriate decisions about the evaluation, diagnosis and treatment of the poisoned patient. Thus, I find it difficult to support the current bill as it is written.

While I certainly understand that public concern exists for the use of a mercury-derived preservative in vaccines and the concerns about the safety of vaccines may be remedied by its removal, I believe that we do the State and its people a disservice by advocating for removal of a chemical, in this dose, that has not been linked to any disease. In addition, I am not sure that this bill can be accomplished without injury to the public health or diminution in the available supply of vaccines.

As I am sure that you are aware, thimerosal is an ethylmercury-based preservative that has been used in vaccines for over 50 years. In recent years, there has been a mistaken belief that ethylmercury in these vaccines is linked to the increase in autism rates throughout the United States. While I am not a developmental pediatrician and will not comment on autism, I can comment on the studies and toxicity of ethylmercury and the risks to children by receiving a rare dose of vaccine containing this preservative.

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March 22, 2007

During the past few years, many publications have reported on evidence that shows no link between autism and mercury. Large epidemiologic studies have compared the risk of autism in children who received thimerosal containing vaccines to those who received vaccines without this preservative[1-4]. These studies showed that the incidence in autism were the same in both groups. In fact, one study showed a higher incidence of autism after thimerosal containing vaccines was removed as a preservative.

In addition, many of the advocates for a link of autism and mercury have used data that focuses on another form of organic mercury, methylmercury. It is important to note that ethylmercury does not behave the same as methylmercury in regard to its toxicity. Methylmercury is more toxic and has been linked in many cases to developmental delays in children born to women who had exposure during their pregnancy. In comparison, ethylmercury has not been linked to any ill effects with low-dose, intermittent exposures.

Advocates have also stated that the symptoms that autistic children display are similar to those who present with a form of mercury poisoning called acrodynia. This is not true. Acrodynia (or Pink's disease) is usually caused by a dermal exposure from inorganic mercury (different from organic mercury). Signs and symptoms of acrodynia include a maculpapular rash, swollen and painful extremities, peripheral neuropathy, high blood pressure and renal effects. These symptoms are clearly not what is seen in an autistic child.

While I applaud your efforts to remove toxins from being available to the children of Kansas and part of my goal as the Director to the MAPCC and MAPEHSU is to prevent poisonings from occurring and help in the treatment of those that are exposed, I cannot support this bill as it is written. To make it a class C misdemeanor for those who give a vaccine containing thimerosal and allow them to be civilly liable, is not scientifically sound. There just isn't a link between autism and mercury by our current evidence. To allow a civil suit against a health care professional because they gave a necessary vaccine with no link to a disease does not make ethical, scientific or common sense. Recent reports reveal that there is a 1:150 chance that a child will develop autism. By the current literature, this will not be due having received a thimerosal containing vaccine and a health care professional should not be held accountable because a vaccine that contained this preservative was given.

If you have any questions or concerns about this information, please feel free to contact me.

Sincerely,

Jennifer Lowry, MD
Medical Director, Mid-America Poison Control Center
Medical Director, Mid-America Pediatric Environmental Health Specialty Unit
University of Kansas Medical Center
Phone: (913) 588-7109
Fax: (913) 588-2350

References:


1. Hviid et al. "Association between thirmerosal-containing vaccine and autism", *Journal of the American Medical Association* 2003; 290: 1763-1766
2. Verstraeten et al. "Safety of thimerosal-containing vaccines: a two phased study of computerized health maintenance organization databases", *Pediatrics* 2003; 112: 1039-1048
3. Heron et al. "Thimerosal exposure in infants and development disorders: a prospective cohort study in the United Kingdom does not show causal association", *Pediatrics* 2004; 114: 577-583
4. Fombonne et al. "Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links with Immunizations", *Pediatrics.* 2006; 118: 139-150

ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

**Ronald B. Phillips**
Vice President, Legislative and Public Affairs

March 21, 2007

The Honorable Jim Barnett
Chairperson, Public Health and Welfare Committee
Room 231-N
300 SW 10th St.
Topeka, Kansas 66612-1563

**Re: SB 1**

Dear Senator Barnett:

The Animal Health Institute (AHI) wishes to express its opposition to SB 1, relating to vaccinations. AHI is the national trade association representing manufacturers of animal health products -- the vaccines, pharmaceuticals, and feed additives that keep pets and livestock healthy and that are used in modern food production. Our members represent approximately 98% of the domestic veterinary biological products market. It is the mission of our members to provide livestock and companion animal owners with safe, effective and innovative medicines needed to protect the health and well-being of animals.

We are concerned that SB 1, if enacted, would endanger the lives of companion animals, horses and livestock in Kansas. It would require the removal of veterinary vaccines from the market in Kansas, leaving animals unprotected against disease and pet owners and livestock producers to deal with the disease, disruption and financial loss.

We offer the following observations:

- Ethyl mercury based preservatives, such as Thimerosal, have a decades-long record of safe use in animals. They are used in the vast majority of veterinary vaccines. There is no evidence that veterinary vaccines using such preservatives have caused any harm to the animals to which they have been administered or to humans.
- Thimerosal-type preservatives are used at very low levels to prevent microbial or fungal growth that could occur with the use of multi-dose vials, which is the most effective way to administer vaccines to many animals in a herd setting. These preservatives are also used to ensure purity in the manufacturing process. Their use is essential to the manufacture of safe, effective and affordable veterinary vaccines.
- Mandating the removal of Thimerosal-type preservatives from veterinary vaccines is unrealistic, impractical and, moreover, unnecessary. It would remove most veterinary vaccines from the Kansas market, leaving Kansas pet owners, horse owners and livestock producers unable to prevent disease in their animals.

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Senate Public Health and Welfare Committee
Attachment #12
March 22, 2007

- Any alternative formulation methods would take considerable time to develop and would necessarily increase retail cost of veterinary vaccines. Also, any possible alternatives would likely include use of single dose vials – a solution that would make the vaccination of livestock on a typical Kansas facility a time-consuming and impractical task. There is no reason to impose these costs and place the health of livestock at risk by banning the use of preservatives that have long been used safely and effectively in veterinary medicine.

If you have any questions or need further information, please do not hesitate to contact me.

Sincerely,

Ronald B. Phillips