

NATIONAL VACCINE INFORMATION CENTER

421-E Church Street, Vienna, VA 22180
(703) 938-0342 Fax: (703) 938-5768
<http://www.909shot.com>

December 18, 2001

Bernard A. Schwetz, DVM, PhD
Acting Commissioner
Food and Drug Administration
The Parklawn Building
5600 Fishers Lane
Rockville, MD 20852

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Rec'd

Dear Dr. Schwetz,

Enclosed is a petition to the Department of Health and Human Services and the Food and Drug Administration asking you to use your authority to remove from the market, Thimerosal-containing vaccines for which there is an existing Thimerosal-free formulation.

Under the National Childhood Vaccine Injury Act of 1986, you have the authority to recall vaccines in order to reduce the risks of adverse reactions.

Sincerely,

Kathryn M. Williams
Co-founder and Vice-President

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02 217
CPI

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND THE FOOD AND DRUG ADMINISTRATION**

PETITION FOR THE IMMEDIATE SUSPENSION)
AND EXPEDITED REVOCATION OF ALL)
VACCINES CONTAINING THIMEROSAL)
FOR WHICH THERE IS AN EXISTING THIMEROSAL-)
FREE FORMULATION)

Docket No. _____

PETITION

Petitioners request that the Secretary of the Department of Health and Human Services and the Commissioner of the Food and Drug Administration take action to order the immediate suspension and the expedited revocation of all vaccines containing Thimerosal, now that Thimerosal-free vaccines are available.

The United States should immediately remove from the market any vaccine that contains the mercury based preservative, Thimerosal.

I. Petitioners

This petition is brought by Kathi Williams, co-founder and Vice-President of the National Vaccine Information Center (NVIC), on behalf of members of NVIC who support the withdrawal of mercury-containing vaccines from vaccine stocks. NVIC is a non-profit nationwide organization dedicated to preventing vaccine injuries and deaths through public education,

improving the safety of vaccines. oversight of vaccine policies, and protecting the informed consent rights of citizens. NVIC, formerly known as Dissatisfied Parents Together (DPT) participated prominently in the development of the National Childhood Vaccine Injury Act, 42 U.S.C. Sec. 300aa-10 et seq. (1988 & 1998 Supp), and has remained deeply involved in monitoring the implementation of the National Vaccine Injury Compensation Program created by the Act. NVIC has member parents whose children have received vaccines containing Thimerosal and have been diagnosed with mercury toxicity and brain damage.

II. The Need for Action

On October 1, 2001, the Institute of Medicine's Immunization Safety Review Committee released a report entitled *Thimerosal Containing Vaccines and Neurodevelopmental Outcomes*. The report stated, "**...the committee recommends the use of Thimerosal-free DTaP, HIB, hepatitis B vaccines in the United States, despite the fact that there might be remaining supplies of Thimerosal-containing vaccine available. The committee could not explore mechanisms by which this could be accomplished.**

However, the committee is concerned that, because of meeting schedules and other requirements- for example the development of official statements on this issue by advisory groups such as the Red Book Committee of the AAP or the ACIP – might delay action. The removal of Thimerosal as a preservative from vaccines on the recommended childhood immunization schedule does not eliminate exposure to Thimerosal from other vaccines, such as DT or influenza, that some infants, children and pregnant women receive. Therefore, the committee recommends that full consideration be given by appropriate professional societies and government agencies to removing Thimerosal from vaccines

administered to infants, or pregnant women in the United States.”¹

Currently every vaccine recommended for children is available without the preservative Thimerosal. Allowing Thimerosal-containing vaccines to remain in use, when Thimerosal-free versions are currently available, unnecessarily exposes American children to a heightened risk of serious adverse reactions. For these reasons, and as set forth below, Thimerosal-containing vaccines should be delicensed and removed from the market immediately.

A. Background

Thimerosal has been used in some vaccines as a preservative since the 1930's. Thimerosal is effective in killing bacteria in opened multi-dose bottles. The Food and Drug Administration Modernization Act of 1997 called for an FDA review of all mercury containing food and drugs which included a review of vaccines that contain Thimerosal. This review was completed in 1999. The FDA recognized that some children could be exposed to a cumulative level of mercury over the first 6 months of life that exceed the federal guidelines on methyl mercury. Thimerosal contains 49.6% mercury by weight and is metabolized to ethyl mercury and thiosalicylate. All guidelines for safe mercury intake are related to methyl-mercury, not ethyl-mercury. Methyl mercury is associated with neurotoxicity in high doses. The Center for Biologic Evaluation and Research (CBER) at the FDA had to assume that the toxicity of the two compounds were equivalent. CBER realized that Thimerosal was present in over 30 licensed vaccines in the United States. According to CBER calculations a 6-month old baby that received all the vaccines on schedule would receive 75 micrograms of mercury from three doses of DTaP,

¹ The Institute of Medicine October 1, 2001, Immunization Safety Review Thimerosal Containing Vaccines and Neurodevelopmental Outcomes

75 micrograms of mercury from three doses of Hib and 37.5 micrograms from three doses of hepatitis B vaccine. The total of 187.5 micrograms exceeds the suggested safe limits published by the EPA.²

B. Professional Committees Recommend Use of Thimerosal-Free Vaccines

Due to any potential risk, the Public Health Service and the American Academy of Pediatrics and the vaccine companies that produce vaccines agreed that Thimerosal-containing vaccines should be removed as quickly as possible. A recommendation was made to forgo the infant dose of hepatitis B vaccine at birth if the mother tested negative for hepatitis B disease, in an effort to provide a wider margin of safety. Pre-term babies were not to be vaccinated with hepatitis B until they reached term gestational age and the weight of at least 5.5 pounds.³

C. Thimerosal Removed from Over the Counter Products

Thimerosal is found in over-the counter products such as ophthalmic solutions and skin ointments. The FDA has already evaluated the safety and effectiveness of many of the over the counter (OTC) uses of mercury compounds as part of its OTC drug review. Many have been found to be not generally recognized as safe and effective.⁴ For many years Thimerosal was used in latex paint to prevent mold from growing in the can. Thimerosal has been eliminated from latex paints, and Merthiolate, a concentrated form of Thimerosal used as an antiseptic, is no

2 Centers for Disease Control. Summer 1999, The Hepatitis Control Report

3 Centers for Disease Control. July 9, 1999, Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service, Morbidity and Mortality Weekly Report.

4 Food And Drug Administration. December 14, 1998, Mercury Compounds in Drugs and Food; Request for Data and Information.

longer used because of serious toxic effects from these products in infants.⁵ The American Academy of Pediatrics state: “Mercury in all forms is toxic to the fetus and children, and efforts should be made to reduce exposure to the extent possible to pregnant women and children as well as the general population.”⁶

D. Risks of Mercury Exposure in Pregnant Women

In March 2001, the FDA issued a Consumer Advisory to pregnant women regarding eating fish that contain high levels of methyl mercury. The Advisory stated, “ While the primary danger from methyl mercury in fish is to the developing nervous system of the unborn child, it is prudent for nursing mothers and young children not to eat these fish as well.”⁷ Unborn babies are more sensitive to the effects of mercury. Premature babies are also more vulnerable because the brain is not developed as in a full-term baby. Very young children are more sensitive to mercury than adults. Mercury in the mother’s body passes to the fetus and can pass to a nursing infant through breastfeeding. If a pregnant woman ingests mercury at high levels, harmful effects that may be passed on from the mother to the developing fetus include brain damage, mental retardation, lack of coordination, blindness, seizures, and an inability to speak. Children poisoned by mercury may develop nervous and digestive system problems and kidney damage.⁸

While the above information refers to mercury poisoning by ingestion or

5 Halsey, Neal A. November 10, 1999, Vol 282, No 18, Journal of the American Medical Association.

6 Goldman, Lynn. July, 2001, Technical Report: Mercury in the Environment: Implications for Pediatricians, Pediatrics.

7 Food And Drug Administration. March 2001, An Important Message for Pregnant Women and Women of Childbearing Age who May Become Pregnant, About the Risks of Mercury in Fish. Consumer Advisory.

8 The Centers for Disease Control - National Immunization Program. July 7,2001. Mercury and Thimerosal FAQ <http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/faqs-mercury>

inhalation of methyl-mercury, the information causes concern for vaccines that contain Thimerosal which is 49.6% ethyl-mercury. All guidelines for safe mercury intake relate to methyl-mercury. No guideline exists for ethyl-mercury.²

E. Influenza Vaccine

The only vaccine licensed for influenza in the United States is made from killed influenza viruses. The vaccine contains 1:10,000 Thimerosal.⁹ The Flu Vaccine is licensed for children 6 months and older. The current recommendation for influenza vaccine includes children in many categories, including those that have chronic disorders, including asthma, have required regular medical follow-up or hospitalization during the preceding year because of chronic disease, children on long-term aspirin therapy and women who will be in the second or third trimester of pregnancy during the influenza season.

F. Europe Changes Protocol

In June 1999, the Agency for the Evaluation of Medicinal Products (EMEA) completed an 18-month investigation into the risks of Thimerosal containing vaccines. EMEA concluded that even though there was no evidence of harm caused by the level of exposure (less than the United States), it would be prudent to promote the general use of vaccines without Thimerosal.²

G. Federal Advisory Panel Makes New Recommendation

Inspections of 225 clinics, pediatrician's offices and family practice offices in mid-September 2001, showed approximately 5.5% of all doses of DTaP, Hib and hepatitis B vaccines

⁹ Wyeth Laboratories. May 16, 1996, Product Insert, Flu Shield.

still contain Thimerosal. The Advisory Commission on Immunization Practices (ACIP) will issue a recommendation in January 2002 to remove all Thimerosal-containing vaccines from the shelves by March 31, 2002.¹⁰

H: Chairman of Government Reform Committee Asks for a Recall

On July 18, 2000, The Government Reform Committee of the House of Representatives held a hearing on the risks of mercury in medicine. Following that hearing, the chairman of the committee, Congressman Dan Burton wrote a letter to Donna Shalala, Secretary of Health and Human Services and said, "Our children are the future of this country. As a Government we have a responsibility to do everything within our power to protect them from harm, including ensuring that vaccines are safe and effective. Every day that mercury-containing vaccines remain on the market is another day HHS is putting 8,000 children at risk. Given that Thimerosal-free vaccines are available and the known risk of mercury toxicity, to leave Thimerosal-containing vaccines on the market is unconscionable."¹¹

Approximately one year later Congressman Burton renewed his request to HHS to recall all childhood vaccines containing Thimerosal stating that we could not leave these products on the shelves until they were used up. "If there is even the slightest chance that a vaccine with mercury could contribute to autism spectrum disorders, learning disabilities, attention deficit disorders or any other neurological condition, then we should act quickly to stop all potential

¹⁰ American Academy of Pediatrics. November 2001, Vaccines with Thimerosal: Out of Offices by March 31, Pediatric News

¹¹ Congressman Dan Burton's Office. October 25, 2000, Chairman Burton Requests Vaccine Recall,

exposure to Thimerosal.”¹²

NOTICE UNDER SECTION 2131

Petitioners hereby give notice of intent to commence suit under Section 21341 of the Public Health Service Act against the Secretary of HHS, the Commissioner of the FDA, and other governmental officials to compel the actions requested above if there is a failure or refusal within the next 60 days to take the proposed actions or otherwise to act more effectively to protect the health of America's children.

Conclusion

The Secretary of the Department of Health and Human Services and the Commissioner of the Food and Drug Administration should take action to order the immediate suspension and the expedited revocation of all vaccines containing Thimerosal, for which there is a Thimerosal-free replacement available.

Certification Under 21 U.S.C. Sec. 10.30(b)(E)

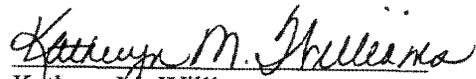
The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are adverse to the petition.

¹² The Committee on Government Reform. October 3, 2001, Press Release

Environmental Impact Statement Under 21 U.S.C. Sec. 10.30(b)(C)

The petitioners hereby state that the relief requested in this petition will have no environmental impact and that, therefore, an environmental assessment is not required under 21 U.S.C. Sec. 25.24

Respectfully submitted,



Kathryn M. Williams
Co-founder and Vice-President
National Vaccine Information Center
421-E Church St.
Vienna, VA 22180
703-938-0342

Butler, Jennie C

From: McClendon, Capri R
Sent: Tuesday, January 15, 2002 12:14 PM
To: Butler, Jennie C
Cc: Fell, Linda; Delman, Dana; Grice, Mary
Subject: Necessary Action/FYI Correspondence; Trac #: 0200217

Importance: High

FROM: Kathryn M. Williams, National Vaccines Information Center

SYNOPSIS: CITIZEN PETITION asking the FDA to remove from the market, Thimerosal containing vaccines for which there is an existing Thimerosal-Free formulation.

Attached is correspondence which requires your Necessary Action or is FYI, as noted on the control sheet.

If you need additional information, please call the Excesses Contact listed on the control sheet.

Thank You, FDA/OC Executive Secretariat



0200217.PDF

ROUTING SLIP
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DATE: JAN 15, 2002

FDA CONTROL NUMBER: 02 217

TRACER #: OS #:

DATE OF CORRESPONDENCE: 12/18/01

DATE INTO FDA: 01/15/02

TO: BERNARD A SCHWETZ HF-1

FROM: KATHRYN M WILLIAMS, NATIONAL VACCINE INFORMATION CENTER

**SYNOPSIS: CITIZEN PETITION ASKING THE FDA TO REMOVE FROM THE MARKET,
THIMEROSAL CONTAINING VACCINES FOR WHICH THERE IS AN EXISTING
THIMEROSAL-FREE FORMULATION.**

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CONTACT/PHONE#: CAPRI R MCCLENDON 301-827-5903

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COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HFA-305	BUTLERJ	NECESSARY ACTION