Chairman Burton Requests Vaccine Recall

COMMITTEE ON GOVERNMENT REFORM 2157 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515

Press Release Contact: Josie Duckett 26 October 2000 (202) 225-5074

The letter to Secretary Shalala (full text below) can be read at http://www.house.gov/reform/letters/10.25.00.pdf

October 25, 2000

The Honorable Donna Shalala, M. D. Secretary of Health and Human Services Washington, DC 20201

Dear Secretary Shalala:

Pursuant to Rules X and XI of the Rules of the House of Representatives, the Committee on Government Reform has oversight of the Department of Health and Human Services. As you are aware, the Committee is conducting an oversight investigation into vaccine safety and policy. As part of this investigation a hearing was conducted on July 18 entitled, "Mercury in Medicine ... Are We Talking Unnecessary Risks?" We received very credible testimony regarding the similarity between symptoms of mercury poisoning and autism and the continued use of thimerosal containing vaccines.

At the time of that hearing, I requested that the Food and Drug Administration recall all thimerosal-containing vaccines from the market. This request was ignored. A petition to the FDA from the parents of vaccine-injured children was ignored. Additional scientific data that has been provided to the FDA regarding the dangers of thimerosal in vaccines has been ignored. I am asking that you personally respond to this request regarding an FDA recall of thimerosal-containing vaccines.

During a review required by the Food and Drug Modernization Act, it was learned that infants receive more mercury in the first six months of life than is considered safe according to federal guidelines. For a twelve-to-fourteen month old child receiving vaccines on the Universal Childhood Immunization Schedule as they are typically delivered (four to six shots in one doctors visit), they may receive forty or more times the amount of mercury than is considered safe according to Environmental Protection Agency (EPA) guidelines. The EPA guidelines were confirmed to be accurate through an independent evaluation conducted by the National Research Council (NRC). The NRC published their mercury report in July.

In testimony to the Committee, the FDA witness stated that each of the vaccines recommended on the Universal Childhood Immunization Schedule are now available for use in a thimerosal free version. While the FDA proposes to "phase out" thimerosal-containing vaccines over time, I implore you to conduct a full recall of these products. If the only action that HUS takes is a gradual phase out, children will continue to be put at risk every day. HHS is leaving supplies of this toxic substance in doctors' offices, at Public Health Clinics, and in managed care facilities. These vaccines will continue to be injected in children for years to come -putting our nation's most vulnerable population - our babies - at risk for mercury poisoning.

We all know and accept that mercury is a neurotoxin, and yet the FDA has failed to recall the 50 vaccines that contain thimerosal. While thimerosal has previously been ruled by the FDA to fit the "generally recognized as safe" standard, when the FDA conducted their Over the Counter (OTC) drug review they changed their minds. The FDA determined that mercury compounds used as active ingredients in OTC drug products were not found to be "generally recognized as safe." Additionally the FDA has not approved any mercury containing compounds as food additives and does not consider any mercury containing compounds to be "generally recognized as safe." On their own website, the FDA states, "lead, cadmium, and mercury are examples of elements that are toxic when present at relatively low levels."

As you know autism rates in this country have skyrocketed. What used to be a very rare condition is now occurring in 1 in 500 children nationwide. In the sixth district of Indiana, 1 in 400 children is autistic. In many areas, the number is as high as 1 in 150 children. The difference in many of these cases of autism is that the symptoms do not appear at birth, but shortly after the delivery of shots in the second year of life. 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 insuring that vaccines are safe and effective. Every day that these 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.

The Chair of the Department of History at the University of Kentucky has provided additional research to the FDA since the July 18 hearing confirming the risks of thimerosal. Each child who is vaccine-injured is a tragedy. From previous experience, we know that even when HITS advised health care professionals to avoid using oral polio and whole cell pertussis vaccines because of the higher rate of adverse events, many clinics and doctors continued to use up their supplies of these vaccines rather than replace them with safer vaccines. How many families were needlessly exposed to live polio and how many children suffered seizures and other tragic injuries for the sake of medical profits? To ignore an avoidable risk and to put 8,000 children a day in harm's way is not only inhumane, it may be criminal.

Please personally respond to this request to recall all thimerosal-containing vaccines by October 31. If you have any questions, please contact Professional Staff Member, S. Elizabeth Clay at 202-225-5074.

Sincerely,

Dan Burton, Chairman

Cc: Honorable Henry Waxman

Ranking Minority Member

The press release (full text below) can be read at http://www.house.gov/reform/press/00.10.26.htm

The letter to Shalala (full text below) can be read at http://www.house.gov/reform/letters/10.25.00.pdf

Testimony from the July 18, 2000 hearing clearly illustrating the risks of mercury in vaccines that was given at the 7/18/00 Congressional Hearing "Mercury in Medicine: Are We Taking Unnecessary Risks?" can be accessed at http://www.house.gov/reform/hearings/healthcare/00.07.18/index.htm.

http://www.house.gov/reform/press/00.10.26.htm

What about Mercury?: Getting Thimerosal Out of Vaccines

By Lisa Reagan

Mothering Issue 105, March/April 2001

http://www.mothering.com/10-0-0/html/10-8-0/10-8-mercury105.shtml

In his opening statement to the House Committee on Government Reform's hearing on mercury and medicine on June 18, 2000, Congressman Daniel Burton (R-Indiana) stated, "We assume that the FDA would protect our children from exposure to any level of mercury through drugs. But that has not been the case. Thimerosal was first marketed in 1930 and has become the most widely used preservative in vaccines. It is present in over 50 licensed vaccines. The FDA recently acknowledged that in the first six months of life children get more mercury than is considered safe by the EPA. The truth is that sometimes kids go to their doctor's office and get four or five vaccines at the same time. My grandson received vaccines for nine different diseases in one day. He might have been exposed to 62.5 micrograms of mercury in one day through his vaccines. According to his weight, the maximum safe level of mercury that he should be exposed to in one day is 1.51 micrograms. This is 41 times the amount at which harm can be caused." Burton's grandson, who was healthy before he received the shots, now suffers from autism.

Burton and Congressman Henry A. Waxman (D-California) have written to Secretary of Health and Human Services Donna Shalala requesting that a panel be convened to look at the mercury issue. "If your position is that we should base our policies on good science and good research, then fine. I agree with you 100 percent. But if you are not willing to do the research, if you are not even willing to ask the questions, then we have a real problem on our hands," Burton said in the letter to Shalala. Burton was a keynote speaker at the National Vaccine Information Center's conference in September 2000.

On July 9, 1999, the US Public Health Service and the American Academy of Pediatrics issued a joint statement recommending the removal of thimerosal from vaccines. On May 31, 2000, the FDA notified vaccine manufacturers that its review of mercury compounds in drugs and foods concluded that reducing or eliminating thimerosal from vaccines is merited.

"One would think that the FDA would have moved aggressively to remove vaccines that contained mercury from the market immediately. They did not....The FDA continues to allow the mercury-containing vaccines to remain on the market. Today, over 8,000 children in America may be given a toxic dose of mercury in their vaccines," said Burton.

The mercury problem's been investigated in many congressional hearings in the last three years. A number of retailers and hospitals, including Walgreens and Wal-Mart, have begun voluntarily to take products containing mercury off their shelves and inventories.

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Another speaker at the NVIC conference, Stephanie Cave, MD, said, "Mercury poisoning and autism have nearly identical symptoms: self-injurious behavior, social withdrawal, lack of eye contact, lack of facial ex pression, hypersensitivity to noise and touch, and repetitive behaviors."

Noting that the EPA safe limit for mercury exposure is .1 micrograms per kilo per day, Cave said, "The mercury has left its mark in the brains and immune systems of these children.... The body gets rid of mercury by secreting bile, but an infant does not produce bile at this age. In the hepatitis B vaccine alone, we are giving 12.5 mcg at birth, 12.5 mcg at a month, 50 mcg at two months, 50 mcg at four months, and 62.5 mcg at 6 months, and if you do your math, we're giving a load of mercury to these children before they can make bile and can get rid of it."

The FDA, Burton said at the conference, determined that mercury compounds used as active ingredients in over-the-counter drug products weren't "generally recognized as safe." Additionally, the FDA doesn't consider any mercury-containing compounds to be "generally recognized as safe." On its own website (www.fda.gov), the FDA states, "Lead, cadmium, and mercury are examples of elements that are toxic when present at relatively low levels."

"How is it that mercury is not safe for food additives and over-the-counter drug products, but it is safe in our vaccines and dental amalgams?" Burton asked. He recommended that all parents who choose to vaccinate request monovalent, mercury-free forms of vaccines.

To see the transcripts of the congressional hearing on mercury in medicine, you can go to www.house.gov/reform/hearings/healthcare/00.07.18/index.htm. To view the ARC Research chart listing the symptoms of mercury poisoning and autism, go to www.autism.com/ari/mercurylong.html.

Notes

1. Karen Pallarito, "DC Hospitals, National Retailers Agree to Ban Mercury-Containing Products," Reuters Health Online, September 27, 2000.

Lisa Regan resides in Williamsburg, Virginia, with her husband, Keith, a portfolio manager, and their son, Collins (3). She is the president of Families for Natural Living (www.FamiliesForNaturalLiving.org), a nonprofit that provides both information to the public and support to families.