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Mercury in Medicine - Taking Unnecessary Risks

A Report Prepared by the Staff of the Subcommittee on Human Rights and Wellness Committee on Government Reform, United States House of Representatives

By Chairman Dan Burton, 3/31/2006 10:37:32 AM

Government Reform.

Executive Summary

Vaccines are the only medicines that American citizens are mandated to receive as a condition for school and day care attendance, and in some instances, employment. Additionally, families who receive federal assistance are also required to show proof that their children have been fully immunized. While the mandate for which vaccines must be administered is a state mandate, it is the Federal Government, through the Centers for Disease Control and Prevention (CDC) and its Advisory Committee for Immunization Practices that make the Universal Immunization Recommendations to which the majority of states defer when determining mandates. Since the early to mid-1990's, Congress has been concerned about the danger posed by mercury in medical applications, and in 1997, directed the Food and Drug Administration (FDA) to evaluate the human exposure to mercury through foods and drugs.

In 1999, following up on the FDA evaluation and pursuant to its authority, the House Committee on Government Reform initiated an investigation into the dangers of exposure to mercury through vaccination. The investigation later expanded to examine the potential danger posed through exposure to mercury in dental amalgams. This full committee investigation complemented and built upon the investigations initiated by two of its subcommittees. In January 2003, the investigation continued in the newly formed Subcommittee on Human Rights and Wellness.

A primary concern that arose early in the investigation of vaccine safety was the exposure of infants and young children to mercury, a known toxin, through mandatory childhood immunizations. This concern had been raised as a possible underlying factor in the dramatic rise in rates of late-onset or "acquired" autism. The symptoms of autism are markedly similar to those of mercury poisoning.

Significant concern has been raised about the continued use of mercury in medical applications decades after the recognition that mercury can be harmful, especially to our most vulnerable population – our children. This report will address one form of mercury in medical applications, Thimerosal, as a preservative in vaccines.

In July 2000, it was estimated that 8,000 children a day were being exposed to mercury in excess of Federal guidelines through their mandatory vaccines.

One leading researcher made the following statement to the Committee in July 2000:

There's no question that mercury does not belong in vaccines.

There are other compounds that could be used as preservatives. And everything we know about childhood susceptibility, neurotoxicity of mercury at the fetus and at the infant level, points out that

we should not have these fetuses and infants exposed to mercury. There's no need of it in the vaccines.

The Food and Drug Administration's (FDA) mission is to "promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use." However, the FDA uses a subjective barometer in determining when a product that has known risks can remain on the market. According to the agency, "at the heart of all FDA's product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great -- especially for products used to treat serious, life-threatening conditions."

This argument – that the known risks of infectious diseases outweigh a potential risk of neurological damage from exposure to thimerosal in vaccines, is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that any possible risk from thimerosal was theoretical: that no proof of harm existed. Upon a thorough review of the scientific literature and internal documents from government and industry, the Committee did in fact find evidence that thimerosal posed a risk. The possible risk for harm from either low dose chronic or one time high level (bolus dose) exposure to thimerosal is not "theoretical," but very real and documented in the medical literature.

Congress has long been concerned about the human exposure to mercury through medical applications. As a result of these concerns, in 1997, Congress instructed the FDA to evaluate the human exposure to mercury through drugs and foods. Through this Congressionally mandated evaluation, the FDA realized that the amount of ethylmercury infants were exposed to in the first six months of life through their mandatory vaccinations exceeded the Environmental Protection Agency's (EPA) limit for a closely associated compound methylmercury. The FDA and other Federal agencies determined that in the absence of a specific standard for ethylmercury, the limits for ingested methylmercury should be used for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA's methylmercury standard and determined that based upon scientific data that it, rather than the FDA's, was the scientifically validated safe exposure standard.

Rather than acting aggressively to remove thimerosal from children's vaccines, the FDA and other agencies within the Department of Health and Human Services (HHS) adopted an incremental approach that allowed children to continue to be exposed to ethylmercury from vaccines for more than two additional years. In fact, in 2001, the Centers for Disease Control and Prevention (CDC) refused even to express a preference for thimerosal-free vaccines, despite the fact that thimerosal had been removed from almost every childhood vaccine produced for use in the United States.

On three occasions in the last 15 years, changes have been made to vaccine policies to reduce the risk of serious adverse effects. First, a transition from oral polio vaccine to injected polio was accomplished in the United States to reduce the transmission of vaccine-induced polio. Second, an acellular pertussis vaccine was developed and a transition from DTP to DTaP was accomplished to reduce the risk of pertussis – induced seizures in children. And third, when the Rotashield vaccine for rotavirus was linked to a serious bowel condition (intussusception), it was removed from the U.S. market. Ethylmercury has been largely removed from every major childhood vaccine manufactured for use in the United States, except the influenza vaccine, which continues to contain trace amounts.

This success, however, does not change the fact that millions of American children were exposed to levels of mercury through vaccines that exceeded comparable federal guidelines. Many parents, and a growing number of scientists, believe that this mercury exposure may have contributed to the

explosive growth in autism spectrum disorders, and neurological and behavioral disorders that this country has experienced. The scientific evidence in this area is considered by some to still be inconclusive, in large part due to the lack of serious, effective inquiry by our health agencies. The federal government has an obligation to vigorously pursue the necessary research to determine the extent of the impact of these heightened exposures to ethylmercury on our population.

A second concern that arose during the investigation was the continued use of mercury in dental amalgams. Mercury has been used as a component in dental fillings since the Civil War era. The American Dental Association and its member dentists have taken a position that the mercury in fillings, which are considered toxic until placed in the tooth, and is considered toxic when removed from the mouth, is completely safe while in the human mouth. This position seems counter even to the ADA-funded research that shows the daily release of small amounts of mercury vapors in the human mouth where dental amalgams are present, as well as minute chipping and swallowing of the mercury fillings over time.

Babies and young children are exposed to this additional mercury. As developing fetuses, babies are exposed to mercury through the placenta. If pregnant women have mercury amalgams, they are unknowingly excreting low levels of mercury on a daily basis to their fetuses. Additionally, children who receive dental services through Medicaid are also potentially exposed to mercury. When these children need dental fillings, because of the low cost, only mercury amalgams are available for use. This concern remains under investigation by the Subcommittee on Human Rights and Wellness.

Findings and Recommendations

Findings

Through this investigation of pediatric vaccine safety, the following findings are made:

- 1. Mercury is hazardous to humans. Its use in medicinal products is undesirable, unnecessary and should be minimized or eliminated entirely.
- 2. For decades, ethylmercury was used extensively in medical products ranging from vaccines to topical ointments as preservative and an anti-bacteriological agent.
- 3. Manufacturers of vaccines and thimerosal, (an ethylmercury compound used in vaccines), have never conducted adequate testing on the safety of thimerosal. The FDA has never required manufacturers to conduct adequate safety testing on thimerosal and ethylmercury compounds.
- 4. Studies and papers documenting the hypoallergenicity and toxicity of thimerosal (ethylmercury) have existed for decades.
- 5. Autism in the United States has grown at epidemic proportions during the last decade. By some estimates the number of autistic children in the United States is growing between 10 and 17 percent per year. The medical community has been unable to determine the underlying cause(s) of this explosive growth.
- 6. At the same time that the incidence of autism was growing, the number of childhood vaccines containing thimerosal was growing, increasing the amount of ethylmercury to which infants were exposed threefold.
- 7. A growing number of scientists and researchers believe that a relationship between the increase in neurodevelopmental disorders of autism, attention deficit hyperactive disorder, and speech or language delay, and the increased use of thimerosal in vaccines is plausible and deserves more scrutiny. In 2001, the Institute of Medicine determined that such a relationship is biologically plausible, but that not enough evidence exists to support or reject this hypothesis.

- 8. The FDA acted too slowly to remove ethylmercury from over-the-counter products like topical ointments and skin creams. Although an advisory committee determined that ethylmercury was unsafe in these products in 1980, a rule requiring its removal was not finalized until 1998.
- 9. The FDA and the CDC failed in their duty to be vigilant as new vaccines containing thimerosal were approved and added to the immunization schedule. When the Hepatitis B and Haemophilus Influenzae Type b vaccines were added to the recommended schedule of childhood immunizations, the cumulative amount of ethylmercury to which children were exposed nearly tripled.
- 10. The amount of ethylmercury to which children were exposed through vaccines prior to the 1999 announcement exceeded two safety thresholds established by the Federal government for a closely related substance – methylmercury. While the Federal Government has established no safety threshold for ethylmercury, experts agree that the methylmercury guidelines are a good substitute. Federal health officials have conceded that the amount of thimerosal in vaccines exceeded the EPA threshold of 0.1 micrograms per kilogram of bodyweight. In fact, the amount of mercury in one dose of DTaP or Hepatitis B vaccines (25 micrograms each) exceeded this threshold many times over. Federal health officials have not conceded that this amount of thimerosal in vaccines exceeded the FDA's more relaxed threshold of 0.4 micrograms per kilogram of body weight. In most cases, however, it clearly did.
- 11. The actions taken by the HHS to remove thimerosal from vaccines in 1999 were not sufficiently aggressive. As a result, thimerosal remained in some vaccines for an additional two years.
- 12. The CDC's failure to state a preference for thimerosal-free vaccines in 2000 and again in 2001 was an abdication of their responsibility. As a result, many children received vaccines containing thimerosal when thimerosal-free alternatives were available.
- 13. The Influenza vaccine appears to be the sole remaining vaccine given to children in the United States on a regular basis that contains thimerosal. Two formulations recommended for children six months of age or older continue to contain trace amounts of thimerosal. Thimerosal should be removed from these vaccines. No amount of mercury is appropriate in any childhood vaccine.
- 14. The CDC in general and the National Immunization Program in particular are conflicted in their duties to monitor the safety of vaccines, while also charged with the responsibility of purchasing vaccines for resale as well as promoting increased immunization rates.
- 15. There is inadequate research regarding ethylmercury neurotoxicity and nephrotoxicity.
- 16. There is inadequate research regarding the relationship between autism and the use of mercury-containing vaccines.
- 17. To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, under-powered, and fatally flawed. The CDC's rush to support and promote such research is reflective of a philosophical conflict in looking fairly at emerging theories and clinical data related to adverse reactions from vaccinations.

Recommendations

- 1. Access by independent researchers to the Vaccine Safety Datalink database is needed for independent replication and validation of CDC studies regarding exposure of infants to mercury-containing vaccines and autism. The current process to allow access remains inadequate.
- 2. A more integrated approach to mercury research is needed. There are different routes that mercury takes into the body, and there are different rates of absorption. Mercury bioaccumulates; the Agency for Toxic Substances and Disease Registry (ATSDR) clearly

states: "This substance may harm you." Studies should be conducted that pool the results of independent research that has been done thus far, and a comprehensive approach should be developed to rid humans, animals, and the environment of this dangerous toxin.

- 3. Greater collaboration and cooperation between federal agencies responsible for safeguarding public health in regard to heavy metals is needed.
- 4. The President should announce a White House conference on autism to assemble the best scientific minds from across the country and mobilize a national effort to uncover the causes of the autism epidemic.
- 5. Congress needs to pass legislation to include in the National Vaccine Injury Compensation Program (NVICP) provisions to allow families who believe that their children's autism is vaccine-induced the opportunity to be included in the program. Two provisions are key: First, extending the statute of limitations as recommended by the Advisory Commission on Childhood Vaccines from 3 to 6 years. Second, establishing a one to two-year window for families, whose children were injured after 1988 but who do not fit within the statute of limitations, to have the opportunity to file under the NVICP.
- 6. Congress should enact legislation that prohibits federal funds from being used to provide products or pharmaceuticals that contain mercury, methylmercury, or ethylmercury unless no reasonable alternative is available.
- 7. Congress should direct the National Institutes of Health to give priority to research projects studying causal relationships between exposure to mercury, methylmercury, and ethylmercury to autism spectrum disorders, attention deficit disorders, Gulf War Syndrome, and Alzheimer's Disease.

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