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Weldon's Letter to Secretary Michael Leavitt Regarding Burbacher and Clarkson Study

Washington, D.C. , Apr 19 - This Letter is Embargoed until 12:01 AM on Thursday, April 21st

The Honorable Michael Leavitt
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Secretary Leavitt,

I want to bring to your attention an important NIH-funded study that was published online today in the journal of the National Institute of Environmental Health Sciences (NIEHS), Environmental Health Perspectives, entitled “Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines containing Thimerosal.” This study was funded through a direct contract with NIEHS and has yielded important information that challenges many of the assumptions used to formulate national public health policy regarding mercury in vaccines, including the potential risk to infants.

In this study, Thomas Burbacher and Thomas Clarkson, two of the leading experts in mercury toxicology and analysis, along with their colleagues, present new data describing how non-human primates handle different forms of mercury. Their results also highlight how much we still do not know about the potential dangers of this mercury-based preservative that is still used in most childhood flu vaccines and many vaccines administered in developing countries.

This striking absence of basic toxicological information about a compound that has been injected into millions of infants led NIEHS to contract with Burbacher and his colleagues to investigate some of these basic questions. In this study, Burbacher and his colleagues show that more inorganic mercury accumulates in the brain after thimerosal exposure through injection than after exposure to methylmercury in food. The accumulation of mercury in the brain after injection with thimerosal occurred even though ethylmercury is cleared from the blood faster than methylmercury. Burbacher et al conclude:

“Data from the current study predicts that while little accumulation of Hg [mercury] occurs over time with repeated vaccinations, accumulation of Hg of the brain of infants will occur. Thus, conclusions regarding the safety of thimerosal drawn from blood Hg clearance data in human infants receiving vaccines may not be valid, given the significantly lower half life of Hg in the brain as observed in the infant macaques [monkeys]” (emphasis added).

Prior to Burbacher’s study, public health authorities relied extensively upon data that suggested that mercury from thimerosal, ethylmercury, was cleared from the blood more quickly than methylmercury (Pichichero, 2002). Based on this result and similar data from other studies (Magos, 2003), many officials assumed, perhaps incorrectly, that ethylmercury was less toxic to infants than methylmercury. Pichichero concluded, based on blood mercury level studies, that “thimerosal in routine vaccines poses very little risk to full-term infants, but that thimerosal-containing vaccines should not be administered to very low birth weight premature infants” (Pichichero, 2002).

Yet until Burbacher's present work, assessments of brain levels of mercury in all its forms after exposure to thimerosal through immunization had never been done. And to date no one has examined whether low levels of mercury in the brain have toxic neurodevelopmental effects. As recently as 2003, public health officials acknowledged that "no data exist on the capacity of low-dose chronic exposure to ethylmercury to harm the developing nervous system" (Offit and Jew, 2003). Ironically, while admitting that the neurotoxicity of thimerosal had never been adequately studied, in this same article, the authors argue that "several facts are reassuring that the level of mercury contained in vaccines was not likely to be harmful." (Offit and Jew, 2003).

Clearly, prior assumptions about the way thimerosal is handled by the human body must be revisited, and follow-up studies must be undertaken. Were thimerosal to be newly introduced to the market today, the Food and Drug Administration (FDA) would require these basic animal toxicology studies before approving its use. I strongly urge that the NIH continue funding these studies until the basic toxicological profile of thimerosal is fully understood.

Now that Burbacher has demonstrated that inorganic mercury accumulates in the brain of monkeys after thimerosal exposure, we must determine the developmental consequence of this accumulation in infants. Non-human primate infants that have been exposed to thimerosal by injection should be assessed by behavioral tests as they develop. Correlating this data with data on the accumulation of mercury in the brain of these infants will provide valuable information about potential toxic effects of thimerosal. The brain samples of these thimerosal-injected infant primates should also be examined directly for evidence of brain damage.

Since the US government promoted the uptake of thimerosal-containing vaccines for decades and continues to recommend the thimerosal-containing flu vaccine for infants, we have an obligation to aggressively fund research designed to answer these basic and critical questions.

Unfortunately, instead of contracting with Burbacher and his colleagues to confirm and extend their results, NIH is contracting directly with researchers to study blood mercury levels in children following receipt of thimerosal-containing vaccines. As Burbacher's study demonstrates, more precise information about blood mercury levels after thimerosal injection is unlikely to yield new information about thimerosal's potential toxic neurodevelopmental effects.

Basic toxicology research into the way mammals process thimerosal should have been done decades ago. Instead of simply making assumptions based on methylmercury, public health officials should have actually studied thimerosal.

With these concerns in mind I would like you to meet with me soon to discuss the proactive steps you and Dr. Zerhouni will be taking to ensure that funding is provided for research following-up on Burbacher's work. This research is critical given that thimerosal remains in many medical products still used in the U.S. including flu vaccines given to millions of children 6 to 23 months of age. Furthermore, tens of millions of thimerosal-containing vaccines are administered to infants around the world each year.

Thousands of parents of children with neurodevelopmental disorders and many members of the press continue to contact me on a regular basis regarding these unanswered questions. I have always been and remain a strong supporter of childhood vaccinations. I support the decision to immunize infants against the flu. Given the lack of information that exists about the toxicity of thimerosal, particularly to vulnerable children, I believe that complete removal of mercury from flu vaccines in the immediate future is the best way to eliminate an exposure to a potential neurotoxin and enhance uptake of the vaccine in the pediatric population. I believe this indicates the need for a proactive approach from HHS.

As a member of the Labor/HHS/Education Appropriations Subcommittee, I look forward to working with you to ensure that research is expedited to fully understand the toxicological profile of thimerosal and its neurodevelopmental effects. Furthermore, I will work with you to enhance the availability of pediatric thimerosal-free flu vaccines.

I would appreciate the opportunity to meet with you to discuss these matters further.

Sincerely,

Dave Weldon, M.D.

Member of Congress

Cc: Dr. Elias Zerhouni
Dr. Julie Gerberding

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