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January 17, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Eschenbach:

As you know, for many years I have been deeply concerned about the safety of America's vaccine supply, including the safety of the mercury-containing substance thimerosal which is used in the production and preservation of vaccines. During my tenure as Chairman of the House Committee on Government Reform (1997-2002), and the subcommittee on Human Rights & Wellness (2003-2004), I held no fewer than 20 hearings to examine the possible correlation between mercury-containing vaccines and the alarming epidemic of autism in this country. A number of credible national and international scientists testified that mercury in vaccines is a contributing factor in developing neurological disorders, including, but not limited to, modest declines in intelligence quotient (IQ), autism, and Alzheimer's disease. And the body of evidence to support that conclusion gets larger every day.

In fact, in November 2007, Dr. DeSoto and Dr. Hitlan (professors in the Department of Psychology, University of Northern Iowa) published a peer-reviewed study in the *Journal of Child Neurology* which concluded: "...that a significant relation does exist between the blood levels of mercury and diagnosis of an autism spectrum disorder." I am aware that the California Department of Public Health recently issued a report concluding that there is no correlation between childhood vaccinations containing thimerosal and autism. However, as the Food and Drug Administration has admitted on several occasions, the expiration date for many mercury-containing vaccines was late 2002. As some mercury-containing vaccines were still probably on the shelf in 2003 – and that is the last birth cohort covered in the California study, and only for age 3 diagnoses – the conclusions of the California study are far from conclusive.

Let me be perfectly clear. I am not, nor have I ever been, anti-vaccine. What I have sought to achieve through my investigations and activism is what every parent wants, to be confident that the vaccines administered to their children – especially those

The Honorable Andrew C. von Eschenbach, M.D

Page 2

vaccines mandated by law – are as safe as possible. That is why I became deeply concerned when I was recently informed about an email dialogue between a parent and both the Centers for Disease Control and Prevention (CDC) and the FDA in which the parent sought clarification on thimerosal use in vaccines.

In summary, and I am paraphrasing based upon what I have been told, the CDC advised the parent that some influenza vaccines and the tetanus and diphtheria vaccine still contain thimerosal. However, the thimerosal-free flu vaccine is available for both children and adults. None of the other vaccines used today in the United States to protect infants and toddlers against infectious diseases contain thimerosal as a preservative. Thimerosal still may be used in the early stages of making certain vaccines; however, it is removed through a purification process. When this process is complete, only trace or insignificant amounts of thimerosal are left (less than 0.3 mcg) and these amounts have no biological effect. The parent was then referred to the FDA when they attempted to follow-up with CDC to ask if any government agency monitors or tests to ensure that the purification process is effective, meaning that the vaccine contains less than 0.3 mcg of thimerosal.

The parent then sent an email to the FDA's Center for Biologics Evaluation and Research (CBER) inquiring about CBER's testing protocol for mercury content. Again, based upon what I have been told, CBER's email response to the parent stated the following: each vaccine lot undergoes thorough testing by the manufacturer; the manufacturer performs specific tests as specified in their license application; the manufacturer submits samples of each licensed vaccine lot and the results of their own tests for potency, safety, and sterility to the Agency; the manufacturer may not distribute a lot of the product into interstate commerce until CBER releases it; CBER will also test the samples provided by the manufacturers for potency, safety and purity; all vaccines are subject to lot release; and, after licensure, monitoring of the product and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the product.

While all of that information is helpful, in the parent's view, and I concur, none of it answered the specific question. I understand after several failed attempts to get a direct response through email from CBER regarding the FDA's testing for mercury content, the parent and a CBER employee eventually spoke over the phone. According to the parent, the CBER employee did not know if manufacturers conducted specific tests for mercury content nor did the CBER employee know if the FDA was measuring mercury content.

As an isolated incident the experience described above would be cause for concern, but I have received similar stories from other parents who had difficulty getting straight answers about thimerosal from the Federal government as well as vaccine manufacturers. With more and more parents refusing vaccinations because of fears about

The Honorable Andrew C. von Eschenbach, M.D

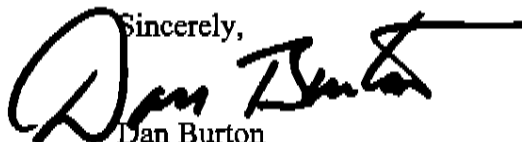
Page 3

thimerosal and mercury, I believe that our Federal health agencies have an obligation to restore public trust in vaccinations by clearly stating that a vaccine truly contains no thimerosal (in other words zero mcg), or trace amounts of thimerosal; and in those instances where thimerosal is removed through a manufacturer's purification process, the assurance that the FDA has monitored and verified that process. To help me better understand the FDA's protocols on mercury content testing, I would appreciate any information you could provide to me on the following:

- Has the FDA determined a safe reference dose for injected ethylmercury and thimerosal for adults and children?
- Does the FDA routinely conduct tests to measure mercury content as part of its lot release program?
- How does the FDA validate in each lot that only a trace amount of mercury remains? In cases where thimerosal is used in the manufacturing process, but is removed by a purification process, is mercury content part of the FDA's safety testing or is it the sole responsibility of the manufacturer?
- Given that thimerosal has not been banned by the FDA, could a vaccine manufacturer distribute vaccines containing more than trace amounts of thimerosal in the United States?

I would greatly appreciate receiving a response from your office, if possible, by the close of business on Monday, February 11, 2008. Should you or your staff have any questions, or need any assistance from my office, please contact Mary Valentino of my staff at (202) 225-2276. I thank you for your personal time and attention to this matter.

Sincerely,



Dan Burton
Member of Congress