Study Misses Link Between Thimerosal and Neurodevelopmental Disorders

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Send letter to journal: Re: Study Misses Link Between Thimerosal and Neurodevelopmental Disorders

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Letter to the Editor:

The recent article, “Safety of Thimerosal-Containing Vaccines: A Two- Phased Study of Computerized Health Maintenance Organization Databases,” by Verstraeteten et al. [1], which failed to find a consistent association between thimerosal in childhood vaccines and neurodevelopmental disorders, has a number of issues that need to be further addressed.

First, the head author, Dr. Thomas Verstraeten, has for the past several years worked for GlaxoSmithKline, a vaccine manufacturer of thimerosal-containing vaccines. In addition, Nancy Pekarek, a company spokeswoman for GlaxoSmithKline, has written that Verstraeten, since leaving the Centers for Disease Control and Prevention (CDC), has worked as an adviser as the study was finalized and prepared for publication. Presently, GlaxoSmithKline, potentially, faces a large number of lawsuits on the very issue that the paper discusses.

Second, this very study was the topic of secrete-closed meetings between members of the CDC and other government organizations, as well as members of the vaccine manufacturers held at Simpsonwood, Georgia from 7-8 June 2000. The transcript of this meeting has been obtained under the Freedom of Information Act. This transcript reveals that the study initially found statistically significant dose-response effects between increasing doses of mercury from thimerosal-containing childhood vaccines and various types of neurodevelopmental disorders. The transcript documents that the data was real and statistically significant for many types of neurodevelopmental disorders, but that the meeting participants expressed that the data had to be “handled.” Despite, discussion about how to “handle” the data, some participants expressed concern that the work that had already been done would be obtained by others through the Freedom of Information Act. In this event, even if professional bodies expressed the opinion that there was no association between thimerosal and neurodevelopmental disorders, it was already too late to do anything. In addition, other participants expressed that the vaccine manufacturers were in a horrible position to be able to defend any lawsuits alleging a relationship between thimerosal and neurodevelopmental disorders, since no one would say with the available data that there was no relationship between thimerosal and neurodevelopmental disorders. Even Verstraeten, in an email following the Simpsonwood meeting, expressed surprise that the data was to be manipulated, stating that ones desire to disprove an unpleasant theory should not interfere with sound scientific methods to evaluate the relationship between thimerosal and neurodevelopmental disorders.

Third, there are also significant issues about the methods used to determine the mercury dose that children received from thimerosal- containing vaccines. The authors, in Table 1 of their

manuscript, completely fail to mention that there were large numbers of thimerosal- free Diphtheria-Tetanus-acellular-Pertussis (DTaP) vaccines administered to children in the Health Management Organizations (HMOs) analyzed. Thimerosal-free DTaP vaccine has been produced by GlaxoSmithKline since 1997. We have personally analyzed the Vaccine Safety Datalink (VSD) database determining that approximately one-third of the children receiving DTaP in the VSD from 1997 through 2000 were immunized with this vaccine, and that the children received thimerosal-free DTaP vaccines in various combinations, with some receiving four doses of thimerosal-free DTaP, some receiving three doses of thimerosal free DTaP and one dose of thimerosal-containing DTaP, some receiving two doses with and two doses without thimerosal, some receiving three with and one without thimerosal, and some receiving all four doses of thimerosal-containing DTaP. In order to evaluate whether Verstraeteten et al., did or did not take this into account, we analyzed Table 1 from their study for the possible cumulative mercury exposures at the various ages of immunization. At one month, the possible mercury exposure was 12.5 micrograms of mercury according to the authors, which is appropriate because there was no potential thimerosal- free DTaP vaccine to take into account. At 2-3 months, the possible cumulative mercury exposure was 37.5-75 micrograms of mercury according to the authors. These potential possible cumulative mercury exposures could be generated by DTP and Hib vaccine separated or combined, or by thimerosal-free DTaP vaccine and Hib (i.e. both DTPH or thimerosal-free DTaP vaccine and Hib vaccine, resulted in children being exposed to 25 micrograms of mercury). At 5-6 months, the possible cumulative mercury exposure was 75 or 125 micrograms according to the authors. The fact that the authors only list these two potential possible cumulative mercury exposure doses show that the authors failed to take into account the thimerosal-free DTaP vaccine made by GlaxoSmithKline, since children receiving one thimerosal-containing DTaP followed by one thimerosal-free DTaP vaccine, in addition to their two doses of hepatitis B vaccine and two doses of Hib vaccine received 100 micrograms of mercury, a mercury dose not mentioned in the table. At 6-7 months, the possible cumulative mercury exposure was 112.5 micrograms of mercury or 187.5 micrograms of mercury according to the authors. These potential possible cumulative mercury exposures show overwhelmingly that there is a significant error in the study. The intermediate mercury values children were exposed to also included: two thimerosal-containing and one thimerosal-free DTaP vaccine, with three doses of hepatitis B vaccine and three doses of Hib vaccine, for a total of 162.5 micrograms of mercury; and two thimerosal-free DTaP and one thimerosal-containing DTaP vaccine, with three doses of hepatitis B vaccine and three doses of Hib vaccine, for a total of 137.5 micrograms of mercury. These calculations indicate that Verstraeteten et al. did not take thimerosal-free DTaP vaccine into account in their study, or if they did, then their paper, as it stands, is replete with inaccurate information.

Additionally, the fact that the VSD data contained large numbers of children who took thimerosal-free DTaP vaccine and large numbers

of children who took thimerosal-containing DTaP vaccine allows a much more direct and powerful way to do the study by comparing these two groups, since this type of analysis would allow for overall evaluation of the effects of increasing doses of mercury from thimerosal in comparison to considerably lesser doses of mercury from thimerosal. We have done just such a study in VSD and found an association between increasing doses of thimerosal and neurodevelopmental disorders. We have previously epidemiologically examined the Vaccine Adverse Event Reporting System (VAERS) for children receiving thimerosal-containing DTaP vaccines in comparison to thimerosal-free DTaP vaccines and the US Department of Education dataset, and both showed an overall and dose-response statistically significant link between increasing doses of thimerosal and neurodevelopmental disorders [2-5]. It also has been observed that children with autism fail to excrete mercury in their hair and show large increases in the amount of mercury in their urine following chelation therapy in comparison to controls [6,7]. These finding are particularly troubling in light of the fact that many authors including Slikker [8] from the Food and Drug Administration have published that thimerosal crosses the blood-brain and placental barriers and results in appreciable mercury content in tissues including the brain, and because it has been shown by Baskin et al. [9] that micromolar concentrations of thimerosal are capable of causing significant damage to neurons. A recently published report from Northeastern University, the University of Nebraska, the USDA, and the Johns Hopkins University has found that thimerosal at picomolar concentrations is a potent neurotoxin since it inhibits the insulin growth factor-1 and the dopamine-stimulated methlyation synthase pathways providing a potential molecular mechanism of how the link between thimerosal in vaccines and neurodevelpmental disorders, reported in our studies, actually increased the incidence of autism and how thimerosal in vaccines through its interaction with the D4 receptor gene may even account for the increase in ADHD as well [10]. It also is in keeping with the many hundreds of peer-reviewed articles published over many decades and from many fields of medicine and science reporting on the harmful effects of thimerosal in humans, animals, isolated neurons, and other systems.

Fourth, there is also a significant issue regarding the inclusion of children who received whole-cell Diphtheria-Tetanus-Pertussis (DTP) vaccine and DTaP vaccine. The Institute of Medicine of the United States' National Academy of Sciences has determined that the evidence is consistent with a causal relationship between whole-cell DTP vaccine and permanent brain damage [11, 12]. In addition, despite the claim by Verstraeteten et al. that encephalopathies following whole-cell DTP occur only rarely, and therefore, this would be unlikely to have influenced the results of the study, some authors, such as Strom [13] reported that 1 in 6,000 children developed a neurological reaction and 1 in 17,000 children died or were left with a permanent neurological defect, and Pollock and Morris [14] who reported that 1 in 8,500 children died or had a neurological disorder following whole-cell pertussis vaccination. Therefore, it is clear that the assumption by Verstraeteten et al. that whole-cell DTP vaccine would have limited

effects upon the results of their study seems incorrect, but rather points to a serious confounder present in their study that makes evaluation of the effect of thimerosal more difficult to discern.

In conclusion, because of a number of very serious issues have been raised and the critical importance of the issue as to whether thimerosal causes neurodevelopmental disorders, we respectfully request that Verstraeten et al. consider withdrawing this study. In order to restore the badly damaged confidence in our much needed vaccine program, it is necessity that past errors be admitted, and that open investigations be conducted on vaccines issues. It is also essential that future vaccine decisions are made by physicians and scientists without even the appearance of conflicts of interest.

Dr. Mark R. Geier has been a consultant and expert witness in cases involving vaccine adverse reactions before the National Vaccine Injury Compensation Program and in civil litigation.

David A. Geier has been a consultant in cases involving vaccine adverse reactions before the National Vaccine Injury Compensation Program and in civil litigation.

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