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Response to Letter to the Editor

A critique that misses the mark

We wish to thank the author for taking the time to read and consider our study (Geier et al., 2018), but unfortunately, the author's comments crucially miss the mark on a number of points.

The author begins his letter by suggesting, " ... the body of clinical studies has detected no risk attributable to low-level uptake of mercury during the first years of life." This statement is completely erroneous and apparently contributes to the author's dismissal of any potential association between mercury exposure from Thimerosal-containing vaccines and neurodevelopmental disorders. The United States' National Academy of Sciences in 2000 issued a report concluding about organic mercury exposure, "Overall, data from animal studies, including studies on nonhuman primates, indicate that the developing nervous system is a sensitive target organ ... On the basis of the body of evidence from human and animal studies, the committee concludes that neurodevelopmental deficits are the most sensitive, well documented effects ... " (National Research Council, 2000). A recent critical review examined clinical, epidemiological, and biochemical studies of the adverse effects from Thimerosal (and its ethylmercury breakdown product) in developing humans and concluded that it was a poison at minute levels with significant adverse effects (Geier et al., 2015). Another recent critical review revealed that of all epidemiological studies evaluating the relationship between Thimerosal-containing childhood vaccines and the long-term risk of an autism spectrum disorder diagnosis, 60% (12 out of 20) found an association (Kern et al., 2016).

The author then undertook an analysis of the Vaccine Adverse Event Reporting System (VAERS) database to evaluate the potential relationship between multiple different types of Thimerosal-containing and Thimerosal-free vaccines and reported neurodevelopmental disorder adverse events. Unfortunately, such a broad sweeping analysis of the VAERS database to evaluate the association between Thimerosal-containing vaccine exposure and neurodevelopmental disorders is not appropriate for multiple reasons.

First, the author fails to consider that the different childhood vaccines examined by the author are administered according to very different schedules. For example, hepatitis B vaccine is recommended to be administered in three doses within the first six months of life starting on the day of birth. By contrast, measles-mumps-rubella vaccine is recommended to be administered as a single dose at 12–15 months of age. As a consequence, the types and frequencies of adverse event reports may be very different based upon the ages of the vaccine recipients.

Second, the author fails to consider that the composition and routes of administration of the various vaccines examined outside of the Thimerosal component are very different. Namely, some, such as diphtheria-tetanus-acellular-pertussis (DTaP) vaccine are injected bacterial toxoids, whereas others such as MMR or varicella are injected live viral vaccines; still others are single-viral antigens such as hepatitis B vaccine; the rotavirus is an orally administered live virus; and finally inactivated polio vaccine (IPV) is an injected killed viral vaccine. Furthermore, other ingredients, such as vaccine adjuvant, are present in

vaccines such as DTaP and completely absent in other vaccines such as MMR, varicella, or rotavirus vaccine. As a consequence, the author has conflated a wide variety of different types of vaccines with different composition, so that any observed or not observed differences in reported adverse events cannot necessarily be ascribed to the potential impacts of Thimerosal administration.

Third, the author fails to consider that the vaccines examined were recommended for administration at different time periods during 1995 through 1999 in the United States. For example, DTaP vaccine was only recommended for routine administration to infants post-1996. As another example, IPV was only recommended for routine administration to infants post-1998. Still further, rotavirus vaccine was only recommended for routine administration to infants 1998–1999. As a result, there are significant differences in the years when Thimerosal-containing and Thimerosal-free vaccines were recommended for administration to children during the 1995–1999 period.

Fourth, the author fails to consider that there are significant differences in the amount of mercury present in the Thimerosal-containing vaccines examined. For example, hepatitis B vaccine contained only 12.5 µg of mercury per dose, whereas DTaP vaccines contained 25 µg of mercury per dose. As a consequence, the potential impact of Thimerosal-containing vaccines on the risk of neurodevelopmental disorders would be expected to be influenced by the dose, which the author fails to consider in his analyses.

Fifth, despite all of the aforementioned limitations in the author's analyses, he did observe a significant association between Thimerosal-containing vaccine exposure and the risk of development delay. Tellingly, the author, once again, dismisses the observed significant association as due to some unknown bias. It would seem the author, like so many others previously examining Thimerosal-containing vaccine safety, is far too unwilling to use sound scientific argumentation and let his standards be dictated by a desire to disprove an unpleasant theory.

It is true the VAERS analysis undertaken in our study was limited in scope (i.e., comparing HibTITER and PedvaxHIB), but as such, it did provide precision in evaluating the potential consequences of Thimerosal exposure in children. The vaccines were recommended for administration at similar ages, the composition and routes of administration were similar, they were administered for similar time periods, and the quantitative differences in mercury content per dose were precisely known. In addition, the method of VAERS analysis employed was similar to that previously described by investigators from the US Centers for Disease Control and Prevention (CDC) to provide quantitative measures of the potential adverse effects of vaccine administration (Chen and Rosenthal, 1996). Finally, as we discuss in great detail in our study, the results observed in our VAERS study are consistent with multiple studies conducted in multiple different countries using different methodologies and provide one more piece of additional evidence revealing the harmful consequences of Thimerosal exposure in human populations.

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As a final important point, we take great offense that the author suggests that we are in favor of " ... skewing public attitude in disfavor of childhood vaccination." As we stated in our study, " ... routine childhood vaccination has been recognized as a public health tool to reduce the morbidity and mortality associated with certain infectious diseases." Our study does not in any way suggest or claim that childhood vaccines are not good. Instead, it provides important scientific evidence showing that the mercurial component, Thimerosal, added to some vaccines is significantly associated with an increased risk of adverse neurodevelopmental outcomes in some children, and, as such, it should be removed from all vaccines as soon as possible.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijheh.2018.11.006>.

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