safeMinds
Sensible Action For Ending Mercury-Induced Neurological Disorders

CDCs Pervasive Pattern of Study Protocol and Design Manipulations after Finding Adverse Outcomes Associated with Vaccines

The Vaccine Safety Datalink (VSD) investigation into thimerosal containing vaccines and adverse neurological outcomes

When FDA announced in July of 1999 that infants who received multiple vaccines preserved with thimerosal may have been exposed to mercury in excess of Federal Safety guidelines, the Center for Disease Control, National Immunization Program (NIP) decided to investigate the issue using the VSD database in an effort to determine if associations existed with regard to exposure to thimerosal containing vaccines and adverse neurological outcomes.

Based on information obtained by SafeMinds in a FOIA request, Dr. Verstraeten and his supervisors at the NIP developed, and later modified several times, a VSD study protocol which resulted in four separate datasets from February 2000 to November of 2003 all of which were designed to assess the impact of neurodevelopmental disorders (NDDs) in children. With each new generation of data, elevated and statistically significant risks were reduced and/or eliminated entirely by changes in the study design protocol, alterations in entrance criteria and statistical methods based on FOIA documents and transcribed minutes to private meetings. Prior to producing reports for each of the four "Generations" Dr. Verstraeten conducted an even earlier analysis of the issues in November and December of 1999. Although he never prepared a formal report on this work, statistical tables obtained by FOIA demonstrate large and statistically significant mercury exposure effects that in many cases exceeded the findings of later reports.

These "Generation Zero" analyses followed a straightforward methodology that was relatively unaffected by the biases and manipulations of the dataset applied in subsequent analyses and are believed to be considerably more sensitive with respect to detecting mercury exposure effects than the later reports. Most notably, these initial analyses compared disease risk in the *highest exposure* population groups to disease risk in *zero exposure* population groups. In addition, the target study population had not yet been subject to numerous exclusions and adjustments applied later, the cumulative effect of which reduced the reported impact of mercury exposure on children's health outcomes.

The results of the Generation Zero analyses are striking and more supportive of a causal relationship between vaccine-based mercury exposure and childhood developmental disorders (especially autism) than any of the results reported later. Relative risks of autism, ADD, sleep disorders and speech/language delay were consistently elevated relative to other disorders and frequently significant. Disease risk for the high exposure groups compared to zero exposure groups ranged from low risks in the range of 1.5 to 2 to high risks in the range of 11 times the risk. The strongest effects occurred very early in life and at the highest levels of mercury exposure; consistent with infant brain development which is most sensitive to the earliest exposures. The elevated risk of autism for the highest exposure levels at one month of age ranged from 7.6 to 11.4 times that for zero exposure levels.

The difference in these results, as compared to later reports, reveal a number of methodological choices that may have been sources of systematic bias in later publications. Of particular concern is the decision to exclude children with less than two polio vaccines but retain all others. The children with less than two polio vaccines may not have been fully immunized and would have been more likely to have been in the zero exposure groups. On the other hand, children with two polio vaccines but with low reported mercury exposures would be more likely to have exposure recording errors. The elimination of zero exposure categories (which served as the reference category for the risk assessment) as well as elimination from consideration exposures in the very highest category had the effect of reducing dispersion in the data by truncating high and low exposures diminishing the ability to discern signal from noise. For a detailed discussion on the four reported generations of VSD data, please see the attached PowerPoint presentations titled *SafeMinds Generation Zero* and *VSD SafeMinds Critique.* *(Link to Exhibit #4)*

Even with alteration in the inclusion criteria, strong dose-dependant associations between thimerosal exposure and several adverse neurological outcomes remained as described in one email from Dr. Verstraeten to his colleagues dated December 17, 1999 titled, “It just won’t go away” where Dr. Verstraeten informs the team of investigators that “these neurological outcomes are very much related (odds of having one when also having the other go from 20 to 100!) As you see some of the RR’s increase over the categories and I haven’t yet found an alternative explanation.” (*Link to Exhibit #5*)

A “draft” report of the data was ultimately generated by Dr. Verstraeten in February 2000. In spite of alterations to the inclusion criteria, highly significant and dose-dependant relationships persisted for ADD/ADHD, speech and language delays, and NDDs, in general. Please note that the relative risk of autism in infants 3 months of age who had received greater than 62.5 mcg of ethyl mercury decreased to 2.48. In the report, Dr. Verstraeten states, “In conclusion, we can state that this analysis does not rule out that receipt of thimerosal containing vaccines in children less than three months of age may be related to an increase risk of neurological developmental disorders. Specific conditions that warrant a more detailed study include autism, dyslalia, misery and unhappiness disorder and attention deficit disorder.” *(Link to Exhibit #6)*

As a result of these findings CDC called a private meeting at Simpsonwood Conference Center in Atlanta where Dr. Verstraeten presented his findings to a small group of CDC and HHS officials, outside experts and vaccine manufacturers. The Simpsonwood meeting, ostensibly held to carefully review the CDC's analysis on the impact of TCVs on child development, instead became a vehicle for making numerous deliberate choices that took positive findings in a single direction -- towards insignificance. Transcribed minutes of this meeting outline several alterations to the original study design that had the net effect of lowering the number of adverse outcomes in the database and reducing the statistical significance of the relationship between those outcomes and exposure to thimerosal. A detailed summary of the events that took place at the Simpsonwood meeting along with verbatim quotes from invited participants was prepared by SafeMinds. *(Link to Exhibit #7)*

For example, Dr. Rhodes, a CDC statistician, made arguments to exclude the lowest exposure cases, claiming that the fact that their exposures were low suggested family behavior that made them unusual. The low rate of adverse outcomes in this group of children, of course, created variability in the data's dependent variable making it possible to establish statistical significance (Page 104). At the same time, he made arguments to exclude some cases that had unusually high thimerosal exposures and adverse outcomes. Any high exposure, high outcome group helped to produce a discernible signal in the data (Page 105). Additionally, he recommended including infants previously excluded because of either congenital or birth disorders. These additions would serve to add "noise" which could obscure the signal (Page 107).

In the case of Raphael B. Stricker, D.[http://grants.nih.gov/grants/guide/notice-files/not93-177.html], for instance, the [[United States Office of Research Integrity |U.S. Office of Research Integrity]] has found the removal of samples from a [[data set]] in order to reach a desired conclusion to be grounds for disbarment from funding.

In their words and actions, the CDC demonstrates a clear bias against reporting positive results and made numerous deliberate choices that took positive findings in a single direction -- towards insignificance**.** Dr. Verstraeten sums up this concern in an email with regard to the Simpsonwood meeting discussions, "I feel we should use sound scientific argument and not let our standards be dictated by our desire to disprove an unpleasant theory." *(Link to Exhibit 8)*