



## **The CDC Knew the Study Design Lacked Power to Detect Associations Between Vaccines and Adverse Neurological Outcomes:**

*But they proceeded to conduct the study without acknowledgement of these shortcomings.*

A basic premise of scientific research is the fact that the larger the number of participants in an investigation, the more robust and accurate the data and the greater power to detect associations. In the CDC publication Verstraeten, T, Davis, RL, DeStefano F, et. al. Safety of thimerosal containing vaccines: a two phased study of computerized health maintenance organizations databases. *Pediatrics* 2003; 112: 1039-1048 this basic premise of research was violated.

For reasons that have never been satisfactorily explained, a large dataset containing information from all three HMOs involved in the study, North California Kaiser (NCK), Group Health Cooperative (GHC) and Harvard-Pilgrim was disaggregated into smaller HMO-specific datasets delineated as HMO-A, HMO-B and HMO-C. As a result of the disaggregation of the data, the power to detect statistically significant relationships was substantially eroded due to the reduction in sample size. In the publication the authors never mention the earlier runs of the data where the datasets had been combined which resulted in numerous statistically significant findings.

This concern was supported by an expert reanalysis of the VSD thimerosal screening analysis by Harland Austin, Dsc and Cathy Lally, MSPH as part of a discovery order filed in the United States Court of Federal Claims in December of 2006. The experts, as part of this reanalysis combined data from HMO-A and HMO-B which resulted in statistically significant findings for tics and sleep disorders which was not reported in the published data. With the combined data from all three HMO's, the P values became appreciably smaller which provides stronger statistical evidence that these positive findings; language delay, tics and sleep disorders, are not due simply to chance. ([Link to Exhibit 9](#))

In fact, one of the study authors, Robert L. Davis acknowledges in an email communication to Frank DeStefano, an employee of the CDC's National Immunization Program and co-author of the study in question on June 26<sup>th</sup> 2000 that they needed to be careful in their analysis of the Harvard-Pilgrim data (HMO-C) "since the main question will be whether or not it (HMO-C) had adequate power to detect an association that was only found when we lumped GHC and NCK together." Obviously, the study authors were aware that the decision to segregate the datasets would result in a lack of consistent significant associations as reported in their investigation published in November, 2003. This purposefully manipulation represents scientific misconduct and falsification of data. ([Link to Exhibit 10](#))

### **In Conclusion**

SafeMinds continues to have grave concerns that the Verstraeten, et al publication of an investigation supported with federal funds represents scientific misconduct and includes falsification and manipulation of statistical methods in an effort to reach a desired result. And sound scientific principles, such as pooling of data, would result in additional associations not detected in the published version of the research. Such misconduct deserves an urgent and complete investigation by an independent counsel with the power to investigate and without inherent conflict of interests in public health policies. Only then can we finally get to the truth and hold accountable all those who have violated the public trust and participated in malfeasant acts of coordinated corruption of science, public policy and transparency of information.