A Brief Review of Verstraeten's "Generation Zero" VSD Study Results

Between February 2000 and November 2003 Thomas Verstraeten and his supervisors at the National Immunization Program produced four separate generations of an analysis designed to assess the impact of vaccine mercury exposures on neuro-developmental disorders in children (see Safe Minds, "Analysis and Critique of CDC's Handling of the Thimerosal Assessment Based on Vaccine Safety Datalink (VSD) Information", October 2003). With each generation, elevated and statistically significant risks were reduced and/or eliminated.

But before these four generations of report were produced, Verstraeten conducted an earlier analysis of these issues in November and December of 1999. He never prepared a formal report on this work, but statistical tables obtained by Safe Minds in a FOIA request (and not previously analyzed) demonstrate large and statistically significant mercury exposure effects that in many cases exceeded the findings of the later reports.

These "Generation Zero" analyses followed a straightforward methodology that was relatively unaffected by biases applied later and was 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 was to reduce 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 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 ranged from lows of 1.5X-2 times to as high as 11 times the disease risk of the zero exposure group.
- Many other outcomes showed no consistent effect, while a few appeared to show a protective effect from vaccine mercury exposure (most likely children with these diagnoses were immunized later).
- The strongest effect was for the highest levels of mercury exposure at the earliest time of exposure, consistent with the idea that infant brain development is most sensitive to the earliest exposures.
- The elevated risk of autism for the highest exposure levels at one month ranged from 7.6 to 11.4 times the zero exposure level. This increased risk level corresponds to the tenfold increase in autism rates seen since vaccine mercury exposures increase starting in 1990

The difference in these results from the later reports reveal a number of methodological choices that may have been powerful sources of bias in later publications, including

- the exclusion of children with less than two polio vaccines: these children would have been most reliably in the zero exposure group, whereas children with two polio vaccines and also with low reported mercury exposure would be more likely to have exposure reporting errors.
- the elimination of zero exposure categories in general as the referent category for risk assessment as well as the reduction in the measured exposure in the highest category: the smaller the spread between high and low exposures, the more an exposure effect will have been diluted.

The findings of the analysis provide strong support for the autism-mercury hypothesis and also support the association of early infant mercury exposure with three specific disorders

	November relative risk (>25 mcg at one month)	December relative risk (>25 mcg at one month)
Autism	7.62	11.35
ADD	3.76	3.96
Sleep disorders	4.98	4.64

These finding also provide evidence of the ways in which data can be manipulated in complex epidemiological analyses. Any population based epidemiological analysis involves numerous subtle choices with respect to study design and reporting, including

- inclusion criteria for the study population
- exposure measures and break points for reporting exposure
- criteria for identification of cases within separate diagnostic categories
- referent exposure levels for the purpose of relative risk calculations
- statistical models of risk (regression techniques, stratification and confounders, etc.), follow up time, quality of fit measures, etc.

Supervisors of such population based studies therefore have wide discretion in the results they choose to report, depending on whether they are interested in reporting a positive or negative finding. In their words and actions, Verstraeten and his supervisors demonstrated clear biases against reporting positive results and made numerous deliberate choices that took positive findings in a single direction, towards insignificance.

The pattern of behavior constitutes malfeasance and should not be permitted to stand. It is time to remove the parties involved from their role in vaccine safety assessment and to subject the VSD data base to open and independent review.