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VACCINE STUDY IN NEW ENGLAND JOURNAL OF MEDICINE WRONG IN CONCLUDING MERCURY EXPOSURES ARE HARMLESS, STATES SAFEMINDS

"STUDY FINDINGS AND LIMITATIONS REQUIRE FURTHER INVESTIGATIONS," SAYS DISSENTING PANEL MEMBER

ATLANTA, GA – A Centers for Disease Control (CDC) study on the relationship between mercury (thimerosal) in vaccines and children's brain functioning draws a misleading conclusion, says one of the study's external consultants, Sallie Bernard, Executive Director of SafeMinds.

"Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years," appearing in the New England Journal of Medicine (NEJM, 9/27/07 issue), concludes that the study "does not support a causal association" between thimerosal and neuropsychological outcomes in children. The conclusion misleads the public, implying without qualification that a relationship has been disproved. In fact, "the study was unable to prove either the presence or absence of a causal relationship," noted Bernard, the panel's only consumer representative.

According to Bernard, unlike gold-standard randomized clinical trials, an observational study such as this cannot address causation. If, however, the findings confirm those of other studies, it can contribute to assessments of causality. This study confirmed associations detected in other studies, such as increased rates of motor and verbal tics and poorer language ability. Replication of previous studies was noted in the text but ignored in the Abstract and Concluding statement, which are the sections routinely read by the wider public.

The study's many limitations preclude sweeping conclusions on thimerosal's effects. The small sample size and few children in the highest and lowest exposure groups reduced the study's precision and ability to establish statistical significance. The study only obtained a 30% participation rate, well below the commonly accepted scientific standard of 70%. Early interventions which may have reduced or eliminated some deficits such as speech delays by age 7 to 10 years were not controlled. An analysis of combined prenatal and postnatal mercury exposures was lacking. Newborns weighing 51bs 8 ounces or less (9% of births) were excluded even though these infants may be more vulnerable to mercury's effects.

The conclusions should have referenced these and other limitations, as well as confirming thimerosal-associated impairments found in other studies, and as a result, called for further investigation. "Children in the U.S. and worldwide are still given vaccines containing mercury. Health officials should be erring on the side of caution," said Bernard. The data set will be made available to other researchers by the CDC, and Bernard hopes other scientists will apply alternative methodologies to study this important public health issue. She has asked the NEJM to publish her dissenting comments when the study appears online at www.nejm.org.

SafeMinds focuses on the role of mercury in neurodevelopmental disorders, including autism. This study did not address autism. A separate CDC-sponsored study investigating thimerosal and autism is underway.