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Julie L. Gerberding, M.D., M.P.H.
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Dr. Julie Gerberding,

I am writing to follow up on our conversation about the article (Verstraeten et. al.,) that will be published in the November 2003 issue of *Pediatrics*. I have reviewed the article and have serious reservations about the four-year evolution and conclusions of this study.

Much of what I observed transpired prior to your appointment a year ago as the Director of the Centers for Disease Control and Prevention (CDC). I am very concerned about activities that have taken place in the National Immunization Program (NIP) in the development of this study, and I believe the issues raised need your personal attention.

I am a strong supporter of childhood vaccinations and know that they have saved us from considerable death and suffering. A key part of our vaccination program is to ensure that we do everything possible to ensure that these vaccines, which are mandatory, are as safe as possible. We must fully disclose adverse events. Anything less than this undermines public confidence.

I have read the upcoming *Pediatrics* study and several earlier versions of this study dating back to February 2000. I have read various e-mails from Dr. Verstraeten and coauthors. I have reviewed the transcripts of a discussion at Simpsonwood, GA between the author, various CDC employees, and vaccine industry representatives. I found a disturbing pattern which merits a thorough, open, timely, and independent review by researchers outside of the CDC, HHS, the vaccine industry, and others with a conflict of interest in vaccine related issues (including many in University settings who may have conflicts).

A review of these documents leaves me very concerned that rather than seeking to understand whether or not some children were exposed to harmful levels of mercury in childhood vaccines in the 1990s, there may have been a selective use of the data to make the associations in the earliest study disappear. While most childhood vaccines now only have trace amounts of mercury from thimerosal containing vaccines (TCVs), it is critical that we know with certainty if children were injured in the 1990s.

Furthermore, the lead author of the article, Dr. Thomas Verstraeten, worked for the CDC until he left over two years ago to work in Belgium for GlaxoSmithKline (GSK), a vaccine manufacturer facing liability over TCVs. In violation of their own standards of conduct, *Pediatrics* failed to disclose that Dr. Verstraeten is employed by GSK and incorrectly identifies him as an employee of the CDC. This revelation undermines this study further.

The first version of the study, produced in February 2000, found a significant association between exposure to thimerosal containing vaccines (TCVs) and autism and neurological developmental delays (NDDs). When comparing children exposed to 62.5 μg of mercury by 3 months of age to those exposed to less than 37.5 μg, the study found a relative risk for autism of 2.48 for those with a higher exposure level. (While not significant in the 95% confidence interval for autism, this meets the legal standard of proof exceeding 2.0.) For NDDs the study found a relative risk of 1.59 and a definite upward trend as exposure levels increased.

A June 2000 version of the study applied various data manipulations to reduce the autism association to 1.69 and the authors went outside of the VSD database to secure data from a Massachusetts HMO (Harvard Pilgrim, HP) in order to counter the association found between TCVs and speech delay. At the time that HP's data was brought in, HP was in receivership by the state of Mass., its computer records had been in shambles for years, it had multiple computer systems that could not communicate with one another (*Journal of Law, Ethics and Medicine Sept. 22, 2000),* and it used a health care coding system totally different from the one used across the VSD. There are questions relating to a significant underreporting of Autism in Mass. The HP dataset is only about 15% of the HMO dataset used in the February 2000 study. There may also be significant problems with the statistical power of the HP dataset.

In June of 2000 a meeting was held in Simpsonwood, GA, involving the authors of the study, representatives of the CDC, and the vaccine industry. I have reviewed a transcript of this meeting that was obtained through the Freedom of Information Act (FOIA). Comments from Simpsonwood, NJ meeting include: (*summary form, not direct quotes*):

- We found a statistically significant relationship between exposures and outcomes. There is certainly an under ascertainment of adverse outcomes because some children are just simply not old enough to be diagnosed, the current incidence rates are much lower than we would expect to see (Verstraeten);
- We could exclude the lowest exposure children from our database. Also suggested was removing the children that got the highest exposure levels since they represented an unusually high percentage of the outcomes. (Rhodes)
- The significant association with language delay is quite large. (Verstraeten);
- This information should be kept confidential and considered embargoed;
- We can push and pull this data anyway we want to get the results we want;
- We can alter the exclusion criteria any we way we want, give reasonable justifications for doing so, and get any result we want;
- There was really no need to do this study. We could have predicted the outcomes;
- I will not give TCVs to my grandson until I find out what is going on here.

Another version of the study - after further manipulation – finds no association between TCVs and autism, and no consistency across HMOs between TCVs and NDDs and speech delay.

The final version of the study concludes that "No consistent significant associations were found between TCVs and neurodevelopmental outcomes," and that the lack of consistency argues against an association. In reviewing the study there are data points where children with higher

exposures to the neuortoxin mercury had fewer developmental disorders. This demonstrates to me how excessive manipulation of data can lead to absurd results. Such a conclusion is not unexpected from an author with a serious, though undisclosed, conflict of interest.

This study increases speculation of an association between TCVs and neurodevelopmental outcomes. I cannot say it was the author's intent to eliminate the earlier findings of an association. Nonetheless, the elimination of this association is exactly what happened and the manner in which this was achieved raises speculation. The dialogue at the Simpsonwood meeting clearly indicates how easily the authors could manipulate the data and have reasonable sounding justifications for many of their decisions.

The only way these issues are going to be resolved – and I have only mentioned a few of them - is by making this particular dataset and the entire VSD database open for independent analysis. One such independent researcher, Dr. Mark Geier, has already been approved by the CDC and the various IRBs to access this dataset. They have requested the CDC allow them to access this dataset and your staff indicated to my office that they would make this particular dataset available after the *Pediatrics* study is published.

Earlier this month the CDC had prepared three similar datasets for this researcher to review to allow him to reanalyze CDC study datasets. However when they accessed the datasets - which the researchers paid the CDC to assemble - the datasets were found to have no usable data in them. I request that you personally intervene with those in the CDC who are assembling this dataset to ensure that they provide the complete dataset, in a usable format, to these researchers within two weeks. The treatment that these well-published researchers have received from the CDC thus far has been abysmal and embarrassing. I would also be curious to know whether Dr. Verstraeten, an outside researcher for more than two years now, was required to go through the same process as Dr. Geier in order to continue accessing the VSD.

You have not been a part of creating this current situation, but you do have an opportunity to help resolve this issue and ensure that confidence and trustworthiness in the CDC and our national vaccination program is fully restored. I would ask that you work with me to ensure that a full, fair, and independent review is made of the VSD database to fully examine this matter. I would like to meet with you at your earliest convenience to move this process forward.

Thank you for your consideration. I look forward to working with you on this urgent matter of great importance to our nation's most precious resource, our children.

Sincerely,

Dave Weldon, M.D.
Member of Congress