

May 22, 2000

Tracy Lieu, MD, MPH
Associate Professor
Department of Ambulatory Care and Prevention
126 Brookline Ave., Suite 200
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Dear Dr. Lieu:

I am sending you a copy of the original protocol of a study in the Vaccine Safety Datalink (VSD) project to examine possible associations between exposure to thimerosal in vaccines and selected neurodevelopmental and renal outcomes. As you can see, the study was designed to have two phases: 1) an initial "screening" analysis of several conditions using automated outcomes data to identify potential associations with specific conditions; and 2) a second phase that would involve a more detailed assessment using a nested case-control or other design of possible associations identified in the first phase. The protocol was reviewed by a Public Health Service working group on health effects of thimerosal in vaccines, as well as internally at CDC and by all the VSD principal investigators.

We have completed the first phase of the study and, on June 21, we will be giving an update to CDC's Advisory Committee on Immunization Practices (ACIP) on thimerosal-related studies. The screening analysis has revealed some possible associations that may deserve more detailed followup. The findings, however, resulted from multiple comparisons and are based on ICD-9 coded computerized diagnoses, with their well-known limitations. To help determine the priority to be given any follow-up studies or whether any policy changes are indicated based on the screening results, CDC considers it essential to corroborate the findings in one or more independent databases. As we have discussed, Harvard-Pilgrim has one of the few databases in the country that could be used in such an analysis. We appreciate your willingness to consider our request, especially given the very short time frame in which the analyses need to be completed. In addition to the original protocol for this study, I am also sending a brief addendum specifying the objectives of the analysis of Harvard-Pilgrim data. The data provided by Harvard-Pilgrim would only be used for the analyses as indicated in the Thimerosal Study protocol and would not be shared with others for different purposes.

Thank you for your consideration of this request. Given the urgency, I would appreciate a decision about whether Harvard-Pilgrim wishes to proceed with the proposed study and an estimated budget as soon as possible.

Sincerely yours,

Frank DeStefano, MD, MPH