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Thimerosal, the Centers for Disease Control and Prevention, and GlaxoSmithKline

Thomas Verstraeten

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To the Editor.—

I am the first author of a recent article on a study undertaken by the Centers for Disease Control and Prevention (CDC) to screen for a potential link between thimerosal-containing vaccines and neurodevelopmental delays.[1] The article has been subject to heavy criticism from antivaccine lobbyists. Their criticism basically comes down to the following two claims: the CDC has watered down the original findings of a link between thimerosal-containing vaccines and autism, and GlaxoSmithKline (GSK) has hired me away from the CDC so as to convince me to manipulate the data further before publication. Because I was responsible for nearly all aspects of this study, including study design, data gathering, data analysis, and writing of the article, I wish to give my opinion on these claims. These are my personal opinions and do not represent the opinion of the CDC or GSK.

Did the CDC water down the original results? It did not. This misconception comes from an erroneous perception of this screening study and other epidemiological studies. The perception is that an epidemiological study can have only 1 of 2 outcomes: either an association is found (or confirmed), or an association is refuted. Very often, however, there is a third interpretation: an association can neither be found nor refuted. Let's call the first 2 outcomes "positive" and "negative" and the third outcome "neutral." The CDC screening study of thimerosal-containing vaccines was perceived at first as a positive study that found an association between thimerosal and some neurodevelopmental outcomes. This was the perception both independent scientists and antivaccine lobbyists had at the conclusion of the first phase of the study. It was foreseen from the very start that any positive outcome would lead to a second phase. Whereas the original plan was to conduct the second phase as a case-control study, we soon realized this would be too time consuming. The validity of the first-phase results needed urgent validation in view of the large potential public health impact. Did the CDC purposefully select a second phase that would contradict the first phase? Certainly not. The push to urgently perform the second phase at health maintenance organization C came entirely from myself, because I felt that the first-phase results were too prone to potential biases to be the basis for important public health decisions. Health maintenance organization C was the only site known to myself and my coauthors that could rapidly provide sufficient data that would enable a check of the major findings of the first phase in a timely manner.

Because the findings of the first phase were not replicated in the second phase, the perception of the study changed from a positive to a neutral study. Surprisingly, however, the study is being interpreted now as negative by many, including the antivaccine lobbyists. The article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended, which is the conclusion to which a neutral study must come. Does a neutral outcome reduce the value of a study? It may make it less attractive to publishers and certainly to the press, but it in no way diminishes its scientific and public health merit. A neutral study carries a very distinct message: the investigators could neither confirm nor exclude an association, and therefore more study is required. The CDC has taken its responsibility and is currently undertaking such additional study. The focus of all attention now should be on ensuring that these new studies are conducted under the most optimal conditions. Continuing the debate of the validity of the screening study is a waste of scientific energy and not to the benefit of the safety of US children or of all children worldwide that have the privilege of being vaccinated. All the discussion on how and why the results presented at different stages of the study may have changed slightly is futile for the same reason. The bottom line is and has always been the same: an association between thimerosal and neurological outcomes could neither be confirmed nor refuted, and therefore, more study is required.

Did GSK hire me away to manipulate the data before publication? Definitely not. This suggestion could be viewed as simply silly, were it not that it offends the ethical integrity of both the company and myself. Although I have been involved in some of the discussions concerning additional analyses that were undertaken after my departure from the CDC, I did not perform any of these additional analyses myself, nor did I instigate them. GSK was at no point involved in any discussions I had with former CDC colleagues on the study, nor were details of these discussions ever discussed between myself and GSK. The company and I had a very clear deal from the very start of my employment that I would finalize my involvement in the study on my own time and keep this involvement entirely separated from my work at GSK. I regard myself as a professional scientist who puts ethical value before any personal or material gains. I believe that I am currently employed by a company that has the same high ethical standards as myself. Therefore, any suggestion that GSK intended to have me manipulate this data is nothing short of an insult to both my and the company's integrity. Although I deeply regret such statements, I call on any party that truly has the safety of our children and the advancement of the health of the world's children at heart to move beyond such pitiable attitudes and focus on the future of the ongoing research.

Thomas Verstraeten, MD, MSc
GlaxoSmithKline Biologicals
1330 Rixensart, Belgium

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