

July 5, 2016

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Re: PFOA and PFOS Levels in Humans and Vaccine-Related Antibody Response in Humans

Dear Dr. Xie,

Thank you for the opportunity to comment on perfluorooctanoate (PFOA) and perfluorooctanesulfonate (PFOS) levels and vaccine-related antibody response in humans as detailed in the June 16<sup>th</sup>, 2016 document, “Systematic Review of Immunotoxicity Associated With Exposure to Perfluorooctanoic acid (PFOA) or Perfluorooctane Sulfonate (PFOS)” from the National Toxicology Program, Department of Health and Human Services.

For more than 40 years, I have conducted a number of studies evaluating vaccine-related immunogenicity and vaccine effectiveness; our primary areas of interest have been with *Haemophilus influenzae*, type B vaccine and influenza vaccine. It is critically important to determine possible modifiers of vaccine immunogenicity and relate these to the potential impact they have on actual vaccine effectiveness. So I welcome your review.

In the above referenced document, it is stated;

**“There is moderate confidence that exposure to PFOA is associated with suppression of the antibody response in humans based on the available studies. The results present a consistent pattern of findings that higher prenatal, childhood, and adult serum concentrations of PFOA were associated with suppression in at least one measure of the anti-vaccine antibody response to common vaccines across multiple studies.”**

I do not believe that the body of data referenced in the report, using the studies noted, support the conclusion that there is “moderate confidence that the exposure to PFOA is associated with suppression of the antibody response in humans based on the available studies.” Rather than provide a detailed study-by-study critique of the studies included in the document analysis, I

would refer you to the comprehensive and scientifically sound analysis of this topic by Ellen Chang and colleagues (Critical Reviews in Toxicology, 2016; 46:4,279-331) (<http://dx.doi.org/10.3109/10408444.2015.1122573>)

Chang and colleagues have accurately concluded in their review that the primary studies that are also included in The National Toxicology Program document do not provide consistent evidence of a significant association between PFOA or PFOS exposure and serological vaccine responses in humans. Also, none of these studies found a significant relationship between PFOA and PFOS levels in humans and increased disease incidence for any of the diseases surveyed.

I urge you reconsider the conclusions of the above referenced document to more closely align with the conclusions of Chang and colleague

My biography can found at;

<http://www.cidrap.umn.edu/about-us/cidrap-staff/michael-t-osterholm-phd-mph>

Thank you for the opportunity to comment on this important issue.

With warm regards,

**[Signature Redacted]**

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