

Statement of the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) to the Task Force on Research Specific to Pregnant and Lactating Women

August 21, 2017

Good morning. I am Sheila Heitzig with the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS), a national pregnancy outcome public-private research model that is coordinated by the American Academy of Asthma, Allergy, and Immunology and is designed to conduct observational studies about medication and vaccine safety in pregnancy.

On behalf of the VAMPSS investigators, we applaud the goals of the Task Force in identifying existing sources of relevant data, proposing methods for bringing together these existing data sources to facilitate amalgamated review, and identifying gaps in research in this topic area. However, we wish to emphasize, as has been well established in more than one comprehensive review, that more than 80% of the prescription medications currently on the market in the U.S. have **no or inadequate** pregnancy safety data. When we consider over-the-counter and herbal products, which are more commonly used by pregnant women than prescription medicine, the number of products with **no or inadequate** pregnancy safety data is likely closer to 100%.

While VAMPSS is one of the national research groups that provides an important source of relevant data on pregnancy safety for both prescription AND over the counter medications and vaccines, we want to make clear that we believe the overarching and overwhelming challenge of the Task Force is going to be in addressing the lack of safety data. There is no existing single or combined set of research programs in this field that is anywhere near sufficiently supported to address this research gap that affects every mother and child in this country.

Thank you.

*The Vaccines and Medications in Pregnancy Surveillance System is a collaboration among the American Academy of Allergy, Asthma, & Immunology (AAAAI); the Organization of Teratology Information Specialists Research Center at the University of California-San Diego (OTIS); the Slone Epidemiology Center at Boston University (SEC); and the Harvard Pregnancy Research Group. For more information on VAMPSS, please contact Sheila Heitzig at [sheitzig@aaaai.org](mailto:sheitzig@aaaai.org), or call (414)-272-6071 or visit [www.aaaai.org/vampss](http://www.aaaai.org/vampss).*