

SMFM Comments to PRGLAC

February 26-27, 2018

On behalf of the Society for Maternal-Fetal Medicine, I am pleased to provide comments to PRGLAC. My name is Katie Schubert.

SMFM was founded in 1977 and is the medical professional society for high-risk pregnancy physicians. We are the leaders in care for pregnant women, and experts in both maternal and fetal health. Our 2,600 members are dedicated to improving care and outcomes for pregnant women. We have long been interested and advocating for better, safer and more effective information about medications taken during pregnancy and lactation, but also to ensuring that maternal health and research during pregnancy and lactation is prioritized.

SMFM's position on research specific to pregnancy is that there should be a presumption of inclusion – that is, that pregnant and lactating women should be included in clinical trials unless there is an obvious or justified reason for excluding them. We see this as a first step in changing the way that we think about research. NIH should build on their work related to gender as a biologic variable by including pregnant females in research involving animal models, as well as changing the consent requirements so that research involving a pregnant woman and fetus should only require *the mother's consent*. This would better align with the current one-parent consent requirement for pediatric research.

We echo the CAMT comments by encouraging PRGLAC to prioritize disease states in which there is a significant need for data about medications used during pregnancy and lactation. Our members are doing all that they can to properly manage chronic conditions as well as emergent issues in pregnancy, but they could be doing so much more with additional research – for example, potentially pregnant women with hepatitis C could be cured, but currently there is no research to test medications to see if they are safe or effective during pregnancy or lactation, and therefore, we cannot recommend or discourage those medications' use. We could be doing better, and women deserve better than being prescribed older drugs that our members know are safe anecdotally. A prioritized list of disease states would be great first step for further research so that we can make an impact on the areas of greatest need.

We also encourage FDA to release its final pregnancy exposure registry guidance to better assist with communicating risks and benefits to patients and providers. Beyond this, we further encourage these registries to do all they can to make the information transparent and easily available for both patients and providers. We are willing and able to assist with raising awareness about research opportunities and inclusion in clinical trials amongst our members and their patients, as well as drilling more specifically down to information surrounding medications used during pregnancy and lactation.

Finally, SMFM strongly believes that NIH needs additional funding that would allow truly prioritizing research involving pregnant women across Institutes. We must expand current research related to pregnancy and lactation generally, as well as to do all we can to encourage industry to engage in clinical research – we must remove barriers to including pregnant women in their work. We are committed to advocating for initiatives that would make strides in these areas.

Thank you for the opportunity to provide these comments. We look forward to continuing to support the work of PRGLAC and improving the health and wellbeing of women and their children.