SMFM Comments to PRGLAC

May 14-15, 2018

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

As you know, SMFM was founded in 1977 and is the medical professional society for high-risk pregnancy physicians. 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.

One area of concern that we would ask PRGLAC to consider is the idea that when medications are approved in adults, they are automatically approved for use in pregnant and lactating women. That is, even though there may not be data because pregnant and lactating women were not included in the clinical trials associated with a drug's approval, those medications are still technically approved in this population. We need to ensure that there is data available, that pregnant and lactating women are included in these studies, so that health care providers and patients can make informed, evidence-based decisions when it comes to their health care and treatment. SMFM's position on research specific to pregnancy is that there should be a presumption of inclusion, with appropriate changes to regulatory framework and ethics policy that would support this idea.

We strongly believe that the NIH needs additional funding that would allow it to prioritize 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.

In terms of recommendations that we believe the task force should make, the task force's discussion throughout its meetings align with the need for additional workforce by way of investigators with expertise in obstetrics, lactation and pharmacology throughout the spectrum of research opportunities – within industry, academics and the federal workspace.

HHS can certainly leverage existing infrastructure to conduct clinical trials that include pregnant and lactating women, but must be supported to develop new multicenter infrastructures as well. Opportunistic studies utilizing existing NICHD networks would be a good place to start.

It will be imperative that new studies include plans for incident pregnancies so that outcomes can be captured, and that there be a central clearinghouse for such data. Pregnancy exposure registries need to be transparent and easily accessible to both providers and consumers. Additionally, trials must be designed to take into account the physiological changes that occur during pregnancy and lactation.

Data collection efforts may take many forms – we believe that leveraging different study designs including but not limited to randomized control trials, comparative effectiveness trials, retrospective analysis via exposure registries and other programs such as PregSource™ would be helpful. We urge PRGLAC to recognize that there may need to be separate paths for drugs already developed and in use,

as well as for generic drugs, and those that have not yet been approved by FDA. Prioritizing disease states or areas of need will help to focus in on where to start.

Overall, we hope PRGLAC recognizes the need for an appropriate regulatory framework that can evaluate medication use in pregnant and lactating women. We also hope that more research in pregnancy and lactation can move forward as a result of this task force's important work. We support a continuation of the task force to further implement these recommendations and to explore new areas of need.

Finally, a key aspect of these recommendations and the work of the task force and broad community will be to ensure public and provider awareness of it. Encouraging a meaningful dialogue that will highlight the importance of research on therapies during pregnancy and lactation will go a long way to increasing awareness of the issue. Such conversations must include not only the impact on the fetus, but the health and wellbeing of the mother as well – that is, the impact of not taking a medication during pregnancy and lactation along with the impact of not breastfeeding on both mother and child must be considered.

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.