

On behalf of the Society for Maternal-Fetal Medicine (SMFM), I am pleased to provide public comment to the PRGLAC Task Force. We appreciate the opportunity to support the work of PRGLAC and are looking forward to the implementation of the recommendations from the September 2018 report to the Secretary.

SMFM is the medical professional society for high-risk obstetricians who have an additional three years of fellowship in maternal-fetal medicine. Our over 4,000 members are physicians, fellows, affiliated health practitioners and practice managers who support the care of high-risk pregnant women. The Society strives to provide education, clinical support and advocacy to further its vision of optimizing the health of high-risk pregnant women and their babies. Our advocacy efforts are aimed at closing health disparities and promoting health equity, prioritizing and strengthening research in pregnant women, ensuring access to MFMs and MFM services to reduce maternal mortality and severe maternal morbidity, and to ensure access to reproductive health services.

First, SMFM strongly supports the inclusion and integration of pregnant and lactating women in the clinical research agenda. We feel it is imperative to addressing the rising maternal mortality and severe maternal morbidity rates in this country that this recommendation be implemented as a priority. We urge PRGLAC to consider this recommendation not just across the NIH, but through all HHS departments as well as to work with industry to ensure adoption of such integration where appropriate.

SMFM also supports strengthening existing research infrastructure that would increase the quality, quantity and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women. Given the aforementioned rising rates of maternal mortality and severe maternal morbidity, the need for an expanded workforce of clinicians and research investigators who have expertise in obstetric and lactation pharmacology and therapeutics is essential to ensuring additional research in pregnant women and lactating women.

We are pleased that the Common Rule has gone into effect and that pregnant women are no longer classified as a vulnerable research population. This will help to close barriers to research in this population. Building on this, however, we urge PRGLAC to specifically consider how to change consent in this population to align with pediatric research. That is, that only the consent of the mother be required to enroll pregnant women in research rather than both parents.

SMFM acknowledges the role of its members and other health professionals and researchers in the implementation of the PRGLAC recommendations. We will work to ensure its members and their patients are aware of the latest information related to research opportunities, the importance of participation in clinical research and the latest data related to specific medications. While the new pregnancy and lactation labeling guidance from the FDA does allow for what we believe is a better format for package inserts – moving from the categories to a description is helpful we continue to be concerned that the new package insert does not provide enough data for enough medications to provide guidance to patients or prescribers on how to treat patients. The work of PRGLAC and implementation of its recommendations specific to prioritizing research in pregnant women and lactating women will help to further the collection of this data and better information sharing to ultimately better inform and guide patients and prescribers.

SMFM supports the creation of a pathway for off-patent products through the NIH and FDA, much like what exists in pediatrics through the Best Pharmaceuticals Act and Pediatric Research Equity Act. It is

essential that such a pathway exist parallel to and separate from the pediatric pathways, not as a replacement to or as an alternative to pediatric research.

Beyond this new pathway, HHS should consider leveraging existing research networks at the NIH, like the Maternal Fetal Medicine Units Network, as well as infrastructure at the FDA, like pregnancy exposure registries or other opportunities that might allow for additional, parallel studies and flexibility and efficiency in research in this population.

Just as leveraging existing network will be critical to furthering this type of research, optimizing registries for pregnancy and lactation will also be necessary. In addition to pregnancy exposure registries, disease-specific or population specific registries might be helpful to further the goal of more research in this space.

In conclusion, thank you again for the opportunity to provide comments today. The Society for Maternal-Fetal Medicine continues to support PRGLAC's work and stands ready to assist in any way possible.