Written Comments of the Society for Birth Defects Research and Prevention (formerly Teratology Society) and the Organization of Teratology Information Specialists to the PRGLAC.

For submission to the public docket.

February 3, 2020

To the members of the PRGLAC Task Force:

These comments are submitted on behalf of the Society for Birth Defects Research and Prevention (BDRP) and the Organization of Teratology Information Specialists (OTIS). Both are professional societies comprised of interdisciplinary scientists and health care providers dedicated to healthy pregnancy outcomes through research, education, and communication. We thank you for the opportunity to contribute to your efforts to drive a cultural change that no longer protects women *from* research, but protects women and their children *through* research.

The initial meeting of the PRGLAC working groups in August 2019 began important conversations towards implementing the recommendations put forward by the PRGLAC panel. With the renewal of the PRGLAC Task Force for the next 2 years, there are key themes that we would like the PRGLAC to continue to consider:

- Leverage existing resources and organizations
    - Expertise is available
    - Many approaches are already in place and we encourage collaboration and coordination
- Ensure and improve training, education, and funding, for:
    - Research programs
    - Health care providers
    - Public understanding of risk

Our specific comments are organized according to the four Working Groups. A more detailed rationale for our suggestions was described in the comments we submitted to the PRGLAC Task Force Members and the public docket in August 2019.

Work Group 1: Research and Training

Increase training for obstetric and pediatric health care providers to include evidence-based training in therapeutics during pregnancy and lactation.

Provide incentives for training and research for early-career faculty and clinicians, as well as NIH-funded research programs, in therapeutics during pregnancy and lactation. Increased long-term funding sources will reduce the knowledge gaps that currently hinder health decision making.

Work Group 2: Regulatory

Remove regulatory barriers to research in pregnant women through mandates and incentives for drug manufacturers to include pregnant women in clinical trials.

Prioritize efforts towards therapeutics used to treat diseases that may be of life-long impact in women such as Crohn's disease and Multiple Sclerosis, and unmet medical needs in pregnancy, such as malaria.

Continue efforts to more clearly communicate risks and benefits in the Pregnancy and Lactation sections of product labeling.

Work Group 3: Communication

Jump start successful public awareness campaigns and evidence-based communication through partnership with professional organizations that have active outreach communication strategies to health care providers and the public.

Optimize registries for medication exposures in pregnancy and lactation through the FDA consistently requiring post-approval pregnancy studies of all eligible products and enforcing FDA recommendations.

- Allocate adequate resources to fulfill this mandate
- Amend the appropriate section of the Federal Food, Drug and Cosmetic Act to expand FDA's authority to, as they see appropriate, require manufacturers of generic products to participate in post-approval pregnancy and lactation studies, and to require manufacturers to initiate and/or participate in multi-drug or disease-based post-approval pregnancy and lactation studies.

Work Group 4: Discovery

Prioritize PRGLAC efforts to drive drug discoveries towards health conditions that lack sufficient information.

Develop risk-benefit guidance communication tools through the use of existing paradigms involving clinical, nonclinical and alternative models to predict risks.

Develop more robust nonclinical testing paradigms to improve human predictions of adverse effects to improve the translatability of nonclinical data to humans.

Develop data linkages with networks of scientists and research programs with existing data, data linkage projects, or potential to develop data linkages.

Establish long-term resources for PRGLAC activities. For example, explore funding from government, industry, and private sources.

In conclusion, we applaud the PRGLAC Task Force for addressing a vital topic. Medical education, regulations, registries and future research need to be expanded, sufficiently funded, and encouraged through oversight and through government action; or else implementation of the Task Force recommendations will founder. BDRP and OTIS are already focused on these topics, have the expertise to help make the recommendations happen, and stand ready to support the Task Force in achieving successful changes to the culture surrounding research needs for pregnant and lactating women.

Respectfully submitted,

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