THE TERATOLOGY SOCIETY

OTIS
Organization of Teratology Information Specialists

Task Force on Research Specific to Pregnant Women and Lactating Women

PUBLIC COMMENTS ON BEHALF OF

THE TERATOLOGY SOCIETY AND

THE ORGANIZATION OF TERATOLOGY INFORMATION SPECIALISTS – OTIS

AUGUST 22 - 23, 2019

ROCKVILLE MD

TERATOLOGY SOCIETY

The Teratology Society is a multidisciplinary group of scientists from a variety of disciplines including researchers, clinicians, epidemiologists, and public health professionals from academia, government and industry who study birth defects, reproduction, and disorders of developmental origin. Teratology Society promotes multi-disciplinary research and exchange of ideas; communicates information to health professionals, decision-makers, and the public; and provides education and training.

OTIS

The Organization of Teratology Information Specialists (OTIS) is a professional scientific society made up of individuals engaged in assessing and evaluating risks to pregnancy and breastfeeding from environmental exposures. OTIS members provide MotherToBaby informational services and support research including MotherToBaby Pregnancy Studies. MotherToBaby offers fact sheets on many agents, and answers inquiries on specific agents from the public and health care providers via phone, email, chat, and texting.

Key Recommendation Themes across Work Groups

For all the Work Group deliberations:

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

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Comments for Working Group 1: Research and Training

Increase the training in obstetrics and pediatrics to include evidence-based training in therapeutics during pregnancy and lactation.

- Broadly available evidence-based training, as found in subspecialty programs such as maternal-fetal medicine, would improve the understanding of the health professionals that provide care to the majority of pregnant and lactating women.

Incentivize training and research for early-career faculty and clinicians, as well as NIH-funded research programs in pregnancy and lactation therapeutics.

Leverage expertise of members in the Teratology Society and OTIS to develop training and research programs.

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Comments for Working Group 2: Regulatory

Utilize expertise in the Teratology Society and OTIS to inform and guide PRGLAC approaches to addressing regulatory considerations.

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

- Model incentives and mandates on the FDA approach used for pediatric testing of drugs.
- Prioritize efforts towards therapeutics used to treat diseases that may be of life-long prevalence in women, conditions specific to pregnancy, or diseases for which there are additional safety concerns and/or unmet medical needs in pregnancy.
- Clinician training programs can begin to address current limitations in understanding risk-benefit information
- Continue efforts to more clearly communicate risks and benefits in the Pregnancy and Lactation sections of product labeling

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Comments for Working Group 3: Communication

Jump start Public Awareness Campaigns & Evidence-based Communication through partnership with professional organizations that are already implementing communication strategies to health care providers and the public.

Optimize registries for pregnancy & lactation: consistently requiring post-approval pregnancy studies for all eligible products & enforcing FDA recommendations:

- Allocation of additional resources to the FDA
- Amendment of *Section 505(o)(3) of FD&C Act (21 U.S.C. 61 355(o)(3)* enabling FDA:
  - To require manufacturers to initiate and/or participate in multi-drug or disease-based post-approval pregnancy and lactation studies,
  - To require manufacturers of generic products to participate in associated product registries if they are active.

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Comments for Working 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, both clinical and nonclinical, and alternative models to predict risks

Develop more robust nonclinical testing paradigms for improved human predictions for 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.**

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Summary

- Medical education, regulations, registries and future research need to be expanded, sufficiently funded, and encouraged
- Establish appropriate oversight and government actions to ensure implementation of the Task Force recommendations.
- OTIS and the Teratology Society are already focused on these topics, have the expertise to help make 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.