

PRGLAC Task Force Meeting Remarks
By KJ Hertz, Director, Federal Affairs
March of Dimes
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Introduction

On behalf of the March of Dimes, I am pleased to provide comments to the PRGLAC task force as it begins its work in this new phase.

March of Dimes, a non-profit, non-partisan organization, fights for the health of all moms and babies. We educate the public about best practices, support lifesaving research, provide comfort and support to families in neonatal intensive care units, and advocate for the health of all moms and babies. March of Dimes promotes the health of women, children and families across the life course, from birth through adolescence and the childbearing years, with an emphasis on preconception, prenatal, inter-conception and infant health.

March of Dimes is a leading member of the Coalition to Advance Maternal Therapeutics, and is devoted to working to raise awareness about research gaps in therapeutics for pregnant and lactating women, and the need for inclusion of pregnant and lactating women in clinical trials. March of Dimes is a strong supporter of the work that PRGLAC has undertaken over the last few years and appreciates your thoughtful consideration of maternal and infant health. We are pleased to have representatives on PRGLAC and look forward to working closely with the task force as it develops implementation plans over the next year.

Background

The topic of today's meeting could not be more important with our nation facing a maternal mortality and morbidity crisis. Tragically, 700 mothers die from pregnancy-related causes each year in the U.S., and more than 50,000 others experience dangerous complications that could have killed them -- making our country the most dangerous place in the developed world to give birth. For women of color, the dangers of giving birth are even more acute. Black mothers are more than three times as likely to die from pregnancy-related complications as their white peers.

These risks can be even more pronounced for women with chronic health conditions that require medications. Of the six million women who are pregnant in the United States every year, roughly 90 percent take at least one medication; yet, the majority of drugs on the market have not been approved as safe and effective for use during pregnancy. Numerous studies show that that most drug trials fail to include or assess potential complications for pregnant or lactating women. As a result, pregnant and lactating women have to choose between forgoing medications to manage health conditions or taking medications without a clear understanding of the risks and benefits.

To help curb maternal deaths and morbidity, medical and behavioral health conditions must be managed and treated before becoming progressively severe. Providing women with continuous

access to the right treatment, including medications, is a critical first step. This may include care for a chronic condition such as diabetes or high blood pressure, treatment for a substance use disorder, or behavioral or other mental health conditions.

March of Dimes supports the task force's 15 recommendations and its efforts to translate these recommendations into more detailed implementation plans through its newly established work groups. We believe that these efforts should all be rooted in the goal of expanding on the availability of research for pregnant and lactating women. In order for this to effectively take place, the research community, industry, health care providers, and consumers will all have to work together to close the gaps in knowledge and research on safe and effective therapies.

March of Dimes supports and encourages the task force to take steps to advance the following recommended policy goals:

Research and Training

- Increase the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant women and lactating women.
- Expand the workforce of clinicians and research investigators with expertise in obstetric and lactation pharmacology and therapeutics.
- Develop separate programs to study therapeutic products used off-patent in pregnant women and lactating women using the NIH BPCA as a model.
- Leverage established and support new infrastructures and collaborations to perform research in pregnant women and lactating women.

Regulatory

- Include and integrate pregnant women and lactating women in the clinical research agenda.
- Remove regulatory barriers to research in pregnant women.
- Reduce liability to facilitate an evidence base for new therapeutic products that may be used by women who are, or may become, pregnant and by lactating women.

Communications

- Create a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women.
- Develop and implement evidence-based communication strategies with health care providers on information relevant to research on pregnant women and lactating women.
- Optimize registries for pregnancy and lactation.

Discovery

- Develop programs to drive discovery and development of therapeutics and new therapeutic products for conditions specific to pregnant women and lactating women.

- Implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research.
- Utilize and improve existing resources for data to inform the evidence and provide a foundation for research on pregnant women and lactating women.

Conclusion

Thank you for the opportunity to comment during today's meeting. March of Dimes stands at the ready to serve as a resource to the task force as it continues its important work to advance the inclusion of pregnant and lactating women in clinical trials and research on new and existing therapies.