Public comment to members of the Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC), May 14–15, 2018

Thank you to the Task Force for your consideration today. This comment is on behalf of a group of 32 researchers, civil society members, affected community members, and organizations interested in the prioritization of pregnant and lactating women in research. Many of the organizations and individuals who signed on to this comment provided feedback in response to the Request for Information (RFI) released ahead of this meeting, but felt it also important to provide additional emphasis during the public comment time today.

In the last two decades, the research community and private sector have made significant strides in terms of closing critical knowledge and data gaps related to drug safety and efficacy. Yet progress has not been standard across the board, and is particularly lagging as it relates to pregnant and lactating women. Pregnant women continue to be excluded from or de-prioritized in clinical research initiatives due to a multitude of factors, such as the complex physiology of pregnant women, the risk studies may pose to the fetus, and the classification of pregnant women as a vulnerable population, among others. This neglect has left pregnant women and their providers to make decisions without adequate information or guidance regarding the safety and efficacy of necessary treatments.

We understand that there are many factors to weigh when developing a research study, including ethical considerations, liability, risk, research needs and design considerations, as well as existing mandates and incentives. However, these factors should not preclude pregnant and lactating women from participating in meaningful and necessary research. Pregnant and lactating women should be able to reap the same benefits from the development of new therapies as other populations and have a right to the assurance that the therapies they are prescribed have been studied specifically to determine safety, efficacy, and appropriate dosing during pregnancy and the postpartum period.

As the Task Force is considering the recommendations it will include in its report to the US Secretary of Health and Human Services (HHS), we urge you to:

- Address U.S. legal and regulatory deterrents to including pregnant and lactating women in clinical trials through legislation and other amendments.
- Support the need for adequate and prioritized funding for research in pregnant and lactating women, and for expanded infrastructure and capacity of research networks capable of conducting trials in this population.
- Improve and/or establish the mechanisms and resources necessary to ensure that data are collected to inform use of existing medicines in pregnant and lactating women, such as replicating the International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) studies conducted under P1026. These studies collect pharmacokinetic and safety data during pregnancy and postpartum, allowing for the comparison of important data points in the 2nd and 3rd trimester with those collected during the postpartum period. These studies also assess drug levels in breast milk, collect neonatal blood samples to look at levels of drug transfer to the infant and the half-life of the drug in the infant, and if breastfeeding, collect infant blood to evaluate the level of the drug in the plasma of the

breastfeeding infant. P1026 evaluates the pharmacokinetics and safety of antiretroviral drugs when used alone and when co-administered with anti-tuberculosis medicines during pregnancy, and when administered with hormonal contraceptives.

- Develop a regulatory framework and guidance to ensure that moving forward, for new therapies under development, safety and other data necessary to inform use in pregnant and lactating women are not left to post-marketing evaluations.
- Allow for the inclusion of pregnant women in phase III trials that are studying drugs for use in treating serious medical conditions that occur in both pregnant and non-pregnant individuals, such as HIV and TB. This includes allowing non-pregnant individuals who become pregnant to continue on investigational therapies with informed consent and careful follow-up in order to collect data on safety and pregnancy outcomes. At the very least, women who are required to cease use of the study drug when pregnancy is recognized should be followed throughout pregnancy to monitor maternal and pregnancy outcomes.
- Implement study and/or data requirements specific to pregnant and lactating women to help shift researcher mindsets from assumed exclusion to presumed inclusion.
- Finally, establish disease-focused registries to complement clinical research initiatives and help capture opportunistic and longer-term data and outcomes for therapies used to treat serious conditions in women who become or are already pregnant, such as the Antiretroviral Pregnancy Registry (APR).

On behalf of the 32 organizations and individuals who signed on to this public comment, we want to thank the Task Force for their work on this issue, and everyone today for their time and consideration.

***This public comment has been endorsed by the following organizations and individuals:**

Organizations

Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), Washington, D.C., USA
Treatment Action Group (TAG), New York, USA
AVAC, New York, USA
Babes Network, YWCA Seattle, Washington, USA
Bailey House, Inc., New York, USA
Blossom Trust, India
Global Media Foundation, West Africa
International AIDS Society (IAS), Switzerland
International Community of Women Living with HIV, East Africa
John Snow Inc., Massachusetts, USA
Kids & Teens Resource Center, Nigeria
TB Proof, South Africa
Tuberculosis and Pregnancy Research Working Group (TBPWG), USA
The Sentinel Project on Pediatric Drug-Resistant TB, Massachusetts, USA
Women and Youth Development Initiative (WOYODEV), Nigeria

Individuals

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