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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information on the Prioritization of Drug, Vaccine, and Dietary Supplement Research Needs for Pregnant, Postpartum, and Lactating Persons

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: The National Institute of Child Health and Human Development (NICHD) seeks nominations for drug, vaccine, and dietary supplement research needs to be considered in the development of a Priority List of Drug, Vaccine, and Dietary Supplement Research Needs for Pregnant, Postpartum, and Lactating Persons. The NICHD is gathering nominations for drugs prescribed for conditions specific to or that co-occur during pregnancy and the postpartum period, including for lactation; dietary supplements that may be used in preparation for, during, or after pregnancy; and vaccines used by pregnant or lactating persons to prevent or treat disease. Additionally, the NICHD is seeking information on factors and processes it could consider in prioritizing these nominations. Nominations are requested from public and private stakeholders such as, but not limited to, researchers, academia, small- and large-scale industries, non-profit organizations, patients, providers, advocacy groups, payors, and federal agencies.

DATES: The request for information is open for public comment and will be accepted through September 29, 2023.

ADDRESSES: Submissions must be submitted via a survey using the following link: https://www.surveymonkey.com/r/PRGLAC23.

FOR FURTHER INFORMATION CONTACT: Questions about this request for information should be directed to Camille Fabiyi, PhD, MPH, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of

Health, 6710B Rockledge Dr., Bethesda, MD 20892, NICHD-PRGLAC@mail.nih.gov, 301–496–3916.

SUPPLEMENTARY INFORMATION: This RFI is intended to obtain information to help advance recommendations outlined in the 2018 Report of the Task Force for Research Specific to Pregnant and Lactating Women (PRGLAC) and 2020 PRGLAC Implementation Plan. In 2016, Congress established PRGLAC through the 21st Century Cures Act to advise the Secretary of Health and Human Services (HHS) regarding gaps in knowledge and research on safe and effective therapies for pregnant and lactating persons. The PRGLAC task force was charged with providing advice and guidance to the HHS Secretary on activities related to identifying and addressing gaps in knowledge and research on safe and effective therapies for pregnant and lactating persons, including the development of such therapies and the collaboration on and coordination of such activities.

The task force developed 15 recommendations based on information gleaned during four open meetings and a request for public comments. The recommendations were submitted in the PRGLAC Report to the HHS Secretary and Congress in September 2018. The report recommended that pregnant and lactating persons be included in the clinical research agenda. The task force published a PRGLAC Implementation Plan in August 2020. A comprehensive review of research conducted for the task force deliberations clearly showed the extremely limited information available on medication use in pregnancy and lactation. Evidence-based answers are required for pregnant and lactating persons and their clinicians to make fully informed choices based on the risks and benefits of medicating or not medicating conditions during pregnancy and lactation. The provision of clinical data is essential to increasing the quantity, quality, and timeliness of research on safety and efficacy of therapeutic products used by pregnant, postpartum, and lactating persons.

Most women use at least one medication during pregnancy and the postpartum period. Many women who become pregnant or are lactating already have chronic conditions needing treatment, in addition to conditions that may arise as a result of pregnancy or lactation. Consequently, because so few studies have been conducted, some prioritization is necessary to determine which drugs, vaccines, and dietary supplements should be studied first.

Information Requested:

The NICHD seeks information and actionable recommendations on research gaps and needs as potential priorities for drugs, vaccines, and dietary supplements used by pregnant, postpartum, or lactating persons.

Comments are strongly encouraged to address challenges and knowledge gaps around drugs, vaccines, or dietary supplements used during pregnancy, the postpartum period, or lactation on health disparity populations. NIH defines health disparity populations as racial and ethnic minority populations, less privileged socioeconomic status (SES) populations, underserved rural populations, sexual and gender minorities (SGM), and any subpopulations that can be characterized by two or more of these descriptions. For more information please refer to NIH definition of Health Disparity.

Respondents are asked to address the following topics in the nomination survey:

(1) Identify the drug, vaccine, or dietary supplement for this nomination. *If applicable, please include generic name of drug or medication.*

(2) Indicate if this nomination is for a:

   a. drug

   b. vaccine

   c. dietary supplement.

(3) Indicate the category of condition for the research question for the nominated drug, vaccine, or dietary supplement. *If there are multiple categories per drug,*

vaccine, or dietary supplement, please submit a separate nomination for each one.

a. Pregnancy- or postpartum-specific conditions (e.g., including but not limited to preterm labor, hyperemesis, labor induction, pre-eclampsia, postpartum hemorrhage).
b. Lactation-specific conditions (e.g., including but not limited to low milk supply, mastitis).
c. General medical conditions that may occur in pregnant, postpartum, and lactating persons (e.g., including but not limited to asthma, depression, diabetes, cardiac disease, STIs, HIV/AIDS, CMV, other infectious disease conditions).

(4) Indicate whether the drug, vaccine, or dietary supplement is used to treat or prevent a condition in:
   a. the mother,
   b. the fetus
   c. both mother and fetus.

(5) Indicate the therapeutic indication that the drug, vaccine, or dietary supplement proposed in this nomination is intended to treat or prevent.

(6) If known, describe the proposed research question and rationale for urgency of need of the nominated drug, vaccine, dietary supplement, including existing evidence and feasibility of the proposed research question.

(7) If known, identify the study design and population that would be most effective in providing the needed evidence for the proposed nomination and the impact this evidence will have on clinical care.

(8) If applicable, describe research-related gaps and needs to enable or facilitate the conduct of proposed studies, such as, but not limited to, biomarkers or other drug

development tools, research infrastructure or collaborations, or workforce training needs.

(9) Describe any other factors to consider in the process of prioritizing research needs for drugs, vaccines, and dietary supplements used by pregnant, postpartum, and lactating persons.

To respond to this RFI, nominations must be made via the nomination form, which will be made available through September 29, 2023. Nominations submitted via e-mail will not be considered. All responses will be compiled into a database that will be reviewed by a committee of stakeholder representatives, to be identified by the NICHD. The review will result in a preliminary priority list. An inaugural stakeholder meeting to review the final priority list and provide updates to the PRGLAC prioritization process will occur at a future date.

Responses to this RFI are voluntary and may be submitted anonymously. Please do not include any personally identifiable information or any information that you do not wish to make public. You may voluntarily include your name and contact information with your response. If you choose to provide NIH with this information, NIH will not share your name and contact information outside of the Federal Government unless required by law. Proprietary, classified, confidential, or sensitive information should not be included in your response. The Government will use the information submitted in response to this RFI at its discretion. Other than your name and contact information, the Government reserves the right to use any submitted information on public websites, in reports, in summaries of the state of the science, in any possible resultant solicitation(s), grant(s), or cooperative agreement(s), or in the development of future funding opportunity announcements. This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the Government to provide

support for any ideas identified in response to it. Please note that the Government will not pay for the preparation of any information submitted or for use of that information.

Alison N. Cernich,

Deputy Director,

Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.

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