Congress of the United States
Washington, DC 20515

January 21, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

We are writing to urge you to extend the charter of the federal Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC), which expired in March 2021, or to establish another advisory committee with a similar range of expertise.

Each year, nearly four million women in the U.S. give birth, and more than three million breastfeed their infants. According to the National Institutes of Health (NIH), although more than 90 percent of pregnant women report taking a medication during pregnancy, only 1 percent of clinical trials mention the words "pregnancy" or "pregnant," and only 0.5 percent mention "lactation." Not enough is known about the effect of most drugs during pregnancy. For example, the rate at which certain drugs are excreted through the kidney may increase by 50 percent during pregnancy. Women with chronic diseases, such as diabetes, hypertension, depression, and asthma need safe and effective medications to manage these ongoing conditions throughout their pregnancy and beyond.

Without reliable data, those who are pregnant or nursing may decide to stop taking necessary medications, increasing risks for both mother and child. In other cases, some may choose not to initiate breastfeeding or may wean earlier than desired because they lack information about the extent of drug transfer into human milk, the potential impacts of the drug on milk production, and the impact of exposure to the infant. Even when drug safety data is available, such data is usually limited, and often does not address how the changes of pregnancy and breastfeeding will affect dosage.

In the context of COVID-19, clinical trials for treatments and vaccines largely excluded pregnant and lactating women, leaving them and their clinicians without clear evidence on safety and efficacy to guide clinical decision-making.

We can and must do better for pregnant and lactating women.

To address this problem, in 2016, Congress established PRGLAC under the 21st Century Cures Act to identify and address gaps in knowledge regarding safe and effective therapies and vaccines for pregnant and lactating women. In 2018, PRGLAC released a Report to Congress that included 15 detailed recommendations to promote the inclusion of pregnant and lactating women in clinical trials. Following release of these recommendations, then-HHS Secretary Alex

Azar extended PRGLAC's charter through March 2021 for the Task Force to create an implementation report, released in August 2020 (PRGLAC Implementation Plan).

Although the development of the PRGLAC recommendations and Implementation Plan marked progress on this issue, much work remains to improve treatment options for pregnant and lactating women. PRGLAC's charter expired on March 13, 2021. To ensure continued implementation of PRGLAC's recommendations, in the Fiscal Year 2022 Appropriations Filed Report, the Labor, Health, Human Services, Education, and Related Agencies Subcommittee included the following language to encourage the implementation of these recommendations:

> *Research on Pregnant and Lactating Women*.—The Committee encourages the Secretary to work with the NIH, FDA, the Office of Human Research Protections (OHRP), and other relevant agencies to implement recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). The Committee encourages the Secretary to direct NIH and FDA to implement guidance and templates surrounding the inclusion of pregnant and lactating individuals within clinical trials in order to require justification for the exclusion of these populations within clinical trials, and to clarify that exclusion of these populations within clinical trials should not be the default practice in the development and evaluation of drugs and therapeutics. The Secretary should work with OHRP and FDA to harmonize FDA regulations with changes to the protected status of pregnant women in federally funded research included in the 2018 revisions to the Federal Policy for the Protection of Human Subjects.

Toward accomplishing this end, we urge you to extend PRGLAC's charter or establish another advisory committee with a similar range of expertise to ensure continued implementation and monitored progress of the steps recommended by PRGLAC. Oversight from a dedicated group of experts is needed to continue to make progress in establishing therapeutic options for pregnant and lactating women.

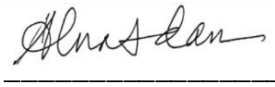
We thank you for your swift attention to this issue. We look forward to hearing from you on your Department's progress implementing PRGLAC's 2020 report and your plans to ensure continued implementation and monitor progress. If we can be of further assistance, please contact Becca Flikier in the Office of Congresswoman Lois Frankel at Becca.Flikier@mail.house.gov or (202) 441-1667.

Sincerely,

Lois Frankel
Co-Chair
Democratic Women's Caucus

Jaime Herrera Beutler
Co-Chair
Caucus on Maternity Care

Lucille Roybal-Allard
Co-Chair
Caucus on Maternity Care



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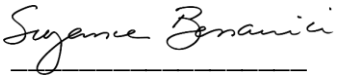

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/s/

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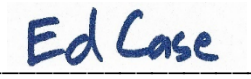

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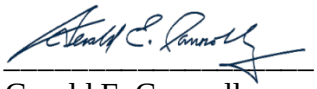

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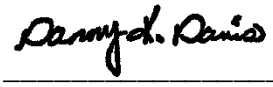

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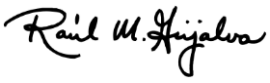

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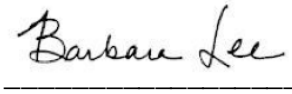

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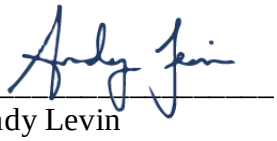

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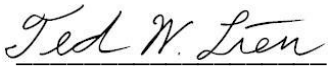

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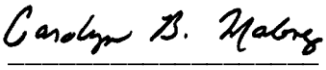

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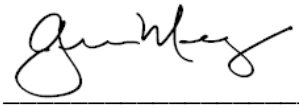

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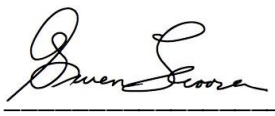

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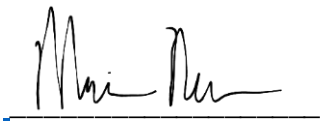

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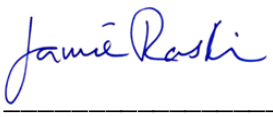

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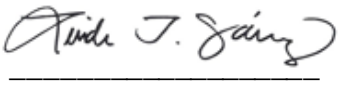

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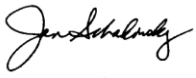

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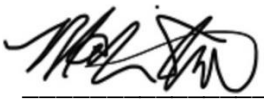

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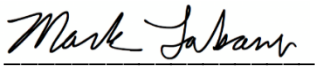

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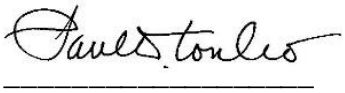

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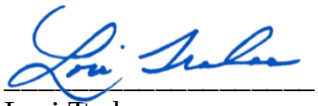

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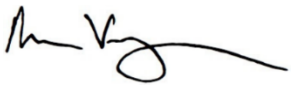

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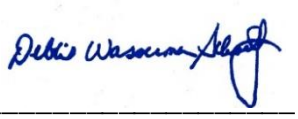

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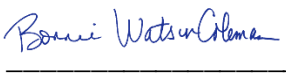

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Cc:
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Dr. Lawrence A. Tabak, Acting Director, National Institutes of Health;
Dr. Janine Austin Clayton, Director, NIH Office of Research on Women's Health, Associate Director for Research on Women's Health, NIH
Dr. Janet Woodcock, Acting Commissioner, Food and Drug Administration
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