



February 26, 2019

The Honorable Jaime Herrera Beutler  
United States House of Representatives  
Washington, DC 20510

Dear Representative Beutler:

Thank you for writing to the Department of Health and Human Services (HHS) about implementation of the proposed recommendations made by the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC or "Task Force"). Secretary Azar asked me to respond on his behalf.

As you know, PRGLAC was established by the 21<sup>st</sup> Century Cures Act to provide advice and guidance to the Secretary. Since PRGLAC was chartered in March 2017, the federal and non-federal members have been working diligently to identify the gaps in our knowledge regarding safe and effective therapies used by pregnant women and lactating women, and to map out what research and other measures should be taken to fill those gaps. The PRGLAC Task Force made excellent progress in assessing the current state of knowledge around therapies used by pregnant women and lactating women. The Task Force's recommendations are comprehensive, covering plans to identify and address gaps in research, the need to address ethical issues surrounding the inclusion of pregnant women and lactating women in clinical trials, and the importance of developing effective communication strategies for use with the health care providers and the public, to name of few.

HHS is reviewing the recommendations provided by the Task Force in order to better facilitate the research and development of safe and effective therapies for pregnant women and lactating women. Additionally, HHS intends to extend the Task Force to continue its important work.

Thank you again for your interest in the Task Force's efforts. If you have any questions, please do not hesitate to contact me at (202) 690-7627. I will also provide this response to Representative Castor.

Sincerely,

A handwritten signature in black ink, appearing to read "Matthew D. Bassett".

Matthew D. Bassett  
Assistant Secretary for Legislation