ADVANCING SAFE MEDICATIONS FOR MOMS AND BABIES ACT OF 2023: SECTION-BY-SECTION SUMMARY

Updating FDA regulations to remove pregnant women as a vulnerable research population

The bill calls for the Food and Drug Administration (FDA) to harmonize its regulations relating to the protection of human subjects with the latest regulations of the Department of Health and Human Services. The current FDA regulations still contain provisions citing "pregnant women" as a vulnerable category of subjects, which may hinder the participation of these populations in research.

Recommendation 1, PRGLAC Report to the HHS Secretary and Congress, September 2018

Establishing and maintaining a federal clearinghouse

To improve awareness about the clinical trials that enroll pregnant and lactating women and to facilitate enrollment, the bill calls for the establishment of a national clearinghouse of educational materials and current information on trials enrolling these populations. The Clearinghouse would also educate stakeholders on the importance of participating in clinical research and the general requirements, commitments, and benefits associated with participation.

Recommendation 13, PRGLAC Report to the HHS Secretary and Congress, September 2018

Creating a coordinating committee

The bill calls for the establishment of a committee to advise on coordinating Federal activities to address gaps in knowledge and research regarding safe and effective therapies for pregnant and lactating women as well as promote opportunities to advance the inclusion of pregnant and lactating women in research; develop and annually update a summary of Federal agency progress toward implementing recommendations laid out in previous PRGLAC reports—namely, the 2018 Report and the August 2020 Report Implementation Plan; identify additional Federal activities to address gaps in knowledge and research; and receive updates on private sector and international efforts to include pregnant and lactating women in clinical research.

Recommendation 15, PRGLAC Report to the HHS Secretary and Congress, September 2018

Conducting a public education campaign

The bill would call for the establishment and implementation of an education campaign that would inform the public on the importance of including pregnant and lactating women in clinical research and which registries and clinical trials include such populations; encourage and facilitate participation by these populations; improve understanding of the role of registries and post-market surveillance activities; encourage pregnant and lactating women to seek additional information about opportunities to participate in clinical research; and encourage providers to make information on clinical research available to pregnant and lactating women.

Recommendation 5, PRGLAC Report to the HHS Secretary and Congress, September 2018

Prioritizing pregnant and lactating women research projects

The bill calls for the NIH Director to carry out priority research projects on existing and new medications prescribed for pregnant and lactating women and to establish a research prioritization process to determine which of the proposed research projects related to this population should receive priority funding. Within 180 days of the legislation's enactment, the NIH Director is required to develop a work plan for funding such research projects and developing the research prioritization process.

Recommendation 9, PRGLAC Report to the HHS Secretary and Congress, September 2018

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