

October 5, 2020, Washington, DC – The Society for Maternal Fetal Medicine (SMFM) issued the statement below to its membership in light of FDA’s announcement regarding Makena (hydroxyprogesterone caproate injection) and its approved generic equivalents:

“Today the U.S. Food and Drug Administration’s Center for Drug Evaluation and Research (CDER) proposed that Makena (hydroxyprogesterone caproate injection) and generic equivalents of Makena be withdrawn from the market. The FDA announcement states that Makena and its approved generic equivalents will remain on the market until the manufacturers decide to remove the drugs or the FDA Commissioner mandates removal. In the interim, the FDA is recommending that health care professionals discuss Makena’s benefits, risks, and uncertainties with their patients to decide whether to use Makena while a final decision is being made.

In the interim, SMFM continues to recommend the unchanged guidance in the [**SMFM Statement: Use of 17-alpha hydroxyprogesterone caproate for prevention of recurrent preterm birth \(October 2019\)**](#) stating that it is reasonable for providers to use 17-OHPC in women with a profile more representative of the very high-risk population reported in the Meis trial. For all women at risk of recurrent sPTB, the risk/benefit discussion should incorporate a shared decision-making approach, taking into account the lack of short-term safety concerns but uncertainty regarding benefit. SMFM will continue to closely follow advances in this area to assure optimal care for women and to provide guidance for maternal-fetal medicine subspecialists.”

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About SMFM

The Society for Maternal-Fetal Medicine (SMFM) is a non-profit, membership organization based in Washington, DC. With more than 4,000 physicians, scientists and women’s health professionals around the world, the Society supports the clinical practice of maternal-fetal medicine by providing education, promoting research and engaging in advocacy to optimize the health of high-risk pregnant women and their babies. SMFM hosts an annual scientific meeting in which new ideas and research related to high risk pregnancies are unveiled and discussed. For more information, visit [SMFM.org](https://www.smfm.org).