SMFM Responds to the FDA's Bone, Reproductive and Urologic Advisory Committee
Clinical Guidance Remains Unchanged

October 30, 2019, Washington, DC – The Society for Maternal-Fetal (SMFM) shared the following information with its membership in light of the recent meeting of the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee.

"Dear SMFM Member,

On October 29, 2019, members of the FDA's Bone, Reproductive and Urologic Drugs Advisory Committee held a meeting and voted 9 to 7 to recommend that the FDA withdraw its approval of Makena. The FDA will consider the committee's recommendation and we expect them to render a final decision in the next several months.

Currently, the SMFM guidance remains unchanged and SMFM advocates that providers at this time have continued access to 17P. We are aware of ongoing studies and will continue to closely follow advances in this area to assure optimal care for women and to provide guidance for maternal-fetal medicine subspecialists.

If you have questions about our clinical guidance or what happened at yesterday's FDA meeting, please contact Beth Steele (esteele@smfm.org) or Katie Schubert (kschubert@smfm.org), respectively.

Sincerely,

Brian K. Iriye, MD
President, Society for Maternal-Fetal Medicine

Mary E. Norton, MD
Chair, Publications Committee"

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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 3,500 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.