17P RECOMMENDATIONS REGARDING FDA ADVISORY COMMITTEE DECISION

Nov 18, 2019

SUMMARY

- In Oct 2019, a Food and Drug Administration advisory committee recommended that approval be withdrawn for Makena – 17-α-hydroxyprogesterone caproate or "17P."
- **This is not the final FDA ruling**; rather, the FDA will take this under advisement and provide a final ruling on the matter in the next several months.
- Both the American College of Obstetrics and Gynecology and the Society for Maternal-Fetal Medicine have issued statements recommending no changes to the existing clinical guidance regarding 17P.
- As recommended earlier, providers should engage in a framework of shared decision-making with at-risk patients to decide whether or not to use 17P. Please see below for more information.

What Led to the FDA Advisory Committee Recommendation?

This recommendation was made based on two studies of 17P that had conflicting results: Meis, et al., published a multicenter study in 2003 that was conducted in the US by the MFMU Network that enrolled 463 women and found a reduction in the rate of recurrent preterm birth among women with a history of a prior spontaneous preterm delivery (Meis, et al., NEJM 2003). In 2019, Blackwell, et al., published a multicenter study ('PROLONG') that was conducted in the US and Europe and enrolled 1800 women and found no reduction in recurrent preterm birth or adverse neonatal outcomes.

The PROLONG study was required by the FDA because 17P was initially approved under an accelerated process. Notably, the recurrent preterm birth rate was lower than expected in this study, and women enrolled in PROLONG had many characteristics that differed from those enrolled in the MFMU study and the typical prematurity population in the US: 90% married, 90% white, average BMI 23, 88% with only one prior preterm birth, 1.5% with a short cervical length. More than 75% of women who were enrolled reside in Ukraine or Russia. Given these differences, it is uncertain whether these data can be directly translated to our population in North Carolina.

How Should I Advise Patients?

Both the American College of Obstetrics and Gynecology and the Society for Maternal-Fetal Medicine have issued statements recommending no changes to the existing clinical guidance regarding 17P.

Recognizing that, despite the lack of immediate safety concerns, weekly injections can require time off from work, transportation and childcare costs, and injection-site pain, the risk/benefit discussion with women at risk of recurrent spontaneous preterm birth should be conducted within a framework of shared decision-making. The "Is 17P Right for Me" handout, available in English and Spanish, may be used as a conversation-starter. (Hard copies can be ordered for free.)

What's Next?

The NC 17P Project of the UNC Center for Maternal and Infant Health will continue to monitor professional society recommendations and new developments surrounding this issue and will continue to provide the public and providers with the most up-to-date information as it becomes available.