**17P**

On October 5, 2020, The Food and Drug Administration's Center for Drug Evaluation and Research (CDER) proposed withdrawal of Makena (hydroxyprogesterone caproate) after results of a confirmatory trial (PROLONG)[1] failed to demonstrate a reduction in recurrent preterm birth rate. At this time, Makena's approval remains in place and the drug remains on the market, as the drug manufacturer has requested a public hearing with the FDA. Currently, both ACOG [2] and SMFM[3] recommendations regarding use of 17P for preterm birth prevention remain unchanged since CDER's proposal and both societies recommend that providers continue to incorporate a shared decision-making approach in the counseling of patients with a history of singleton spontaneous preterm birth.

The MNPQC will continue to closely follow any advances and additional information in this area and will provide updates and clinical guidance as they become available.

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[1] Blackwell SC, Gyamfi-Bannerman C, Biggio JR, Chauhan SP, Hughes BL, Louis JM, et al. 17-OHPC to prevent recurrent preterm birth in singleton gestations (PROLONG study): a multicenter, international, randomized double-blind trial. Am J Perinatol 2020; 37 (2): 127-136

[2] https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2019/10/clinical-guidance-for-integration-of-the-findings-of-the-prolong-study

[3] SMFM Statement: Use of 17-alpha hydroxyprogesterone caproate for prevention of recurrent preterm birth. Am J Obstet Gynecol. 2020 Jul;223(1)