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VPS Statement on PROLONG Trial/Clinical Use of 17P

Valley Perinatal is committed to practicing in accordance with the guidance of federal regulatory bodies and our professional societies. The recent release of the PROLONG trial results have raised many questions regarding the role of 17-hydroxyprogesterone caproate (17-OHPC) as a viable treatment option. 17-OHPC was brought to market through the Orphan Drug Act (ODA), which allows medications targeted to underserved populations to have an expedited pathway for FDA clearance.

Data on the efficacy of 17-OHPC produced in a study by Meis et al was evaluated by the FDA as part of the initial approval process. Since 17-OHPC was made commercially available, there have been a number of studies that questioned the efficacy of the medication and searched for characteristics of women that would have a more consistent response.

A stipulation of approval of 17-OHPC through the ODA by the FDA was the completion of a larger study to confirm the initial findings of the Meis trial. This confirmatory study is the PROLONG trial, which was recently published and revealed no efficacy for its primary endpoints. Four days after publication of the study findings, an FDA Advisory Board recommended pulling 17-OHPC off the market; a final decision from the FDA is pending at this time. In the interim, ACOG and SMFM have released practice advisory statements acknowledging the conflicting data on treatment efficacy, while also advocating individualization of treatment choices based on the patient's specific history.

Per the SMFM, 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. It is important to consider that 17-OHPC is associated with substantial health care costs, injection-site pain, and extra patient visits and that long-term potential maternal and neonatal effects are unknown"*.

Based on a cumulative review of relevant publications and recent events, Valley Perinatal no longer considers 17-OHPC to be an assumed treatment choice for women with a history of preterm birth. Interventions for the prevention of recurrent preterm birth should be individualized and include a range of options (vaginal progesterone, cerclage placement, behavioral changes, increased clinical surveillance, or 17-OHPC) based on clinical judgement. We are grateful to be involved in the care of your patients and will continue to work collaboratively with referring practices to improve patient outcomes.