



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS



Society for Maternal-Fetal Medicine

Information Update on 17 α -Hydroxyprogesterone Caproate (17P) from The American College of Obstetricians and Gynecologists and The Society for Maternal-Fetal Medicine

On April 1, 2011, The American College of Obstetricians and Gynecologists (“the College”) and the Society for Maternal-Fetal Medicine (“SMFM”) with other medical and clinician groups issued a statement regarding Makena™ and compounded 17 α -hydroxyprogesterone caproate (17P). The College and SMFM issued an additional statement on April 28, 2011, in response to the numerous questions the organizations had received about the implications of prescribing compounded 17P (“the Statements”).

The College and SMFM have been made aware that parts of the Statements may have been taken out of context and used to interfere with physician judgment in prescribing for patients. The Statements were not intended to be used by private or public payers as a basis for interfering with a treating physician’s medical judgment or denying patient access to Makena™. The Statements were also not meant to suggest that Makena™ and compounded 17P are identical products. As a result, the College and SMFM are providing the following information:

- Physicians should be permitted to prescribe drugs based upon medical considerations and patient need and access.
- Physicians should be able to prescribe Makena™ or compounded 17P based on accepted medical indications after discussion with the patient.
- Physicians prescribing Makena™ or compounded 17P should be aware of the U.S. Food and Drug Administration’s (FDA) statement on Makena™ (<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm>).
- Physicians should understand the inherent differences between an FDA-approved manufactured product and a compounded preparation (See: ACOG Committee Opinion No. 387 Pharmaceutical Compounding, November 2007, <http://www.acog.org/partners/greenjournal/co387.pdf>).

Furthermore, it has been the College and SMFM’s understanding, based upon peer-reviewed published articles, that some of the drugs from the studies used to obtain FDA approval of Makena™ were compounded. The College and SMFM would like to clarify that the study drugs were manufactured in compliance with FDA guidelines for Good Manufacturing Practices.

Date: October 13, 2011