



NEWS

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SOCIETY FOR MATERNAL-FETAL MEDICINE COMMENDS FDA ON MAKENA ANNOUNCEMENT

FDA Announcement Allows Continued Compounding of Drug

WASHINGTON, D.C., March 30, 2011 – The Society for Maternal-Fetal Medicine (SMFM) weighed in on today’s FDA announcement to continue to allow pharmacies to compound hydroxyprogesterone caproate, also known as 17P. This FDA announcement comes in response to an outcry from SMFM, ACOG and others regarding the costs of the just-released pharmaceutical version of the drug. The new drug, Makena, made by KV Pharmaceuticals, is being sold at \$1,500 per dose as opposed to the pharmacy compound which typically costs \$10 to \$20 per dose.

“The Society for Maternal-Fetal Medicine commends the FDA on its recently released position that it will exercise enforcement discretion with respect to compounding hydroxyprogesterone caproate,” stated George Saade, president of SMFM. “This action will ensure that this life-saving treatment will continue to be available for all those who need it. Affordable access to hydroxyprogesterone caproate is critical in ensuring the health and full-term birth of babies in the U.S.”

Typically, once a drug is approved by the FDA, pharmacy compounding is no longer allowed. The FDA stated that KV Pharmaceuticals had sent “letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena.” The FDA statement goes on to state that “This is not correct.”

The research for Makena was funded by taxpayer dollars which funded the initial clinical trial in 2003 under the auspices of the National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health. Additional trials were funded by NICHD through its multicenter network of medical institutions over several years. The studies found that pregnant women who had previously delivered a preterm baby, if treated with weekly injections of hydroxyprogesterone caproate, had fewer preterm babies, and the babies had fewer complications of prematurity. The drug was also found to be effective in both African American and Non-African American women. An economic analysis authored by Dr. Balit of Case Western Reserve University showed that weekly injections of compounds similar to Makena, given to at risk women, would dramatically reduce the incidence of premature births—and more over it could save the health care system at least \$2 billion per year.

“When you consider that the ideal treatment for these at-risk women is administered during weeks 16-36 of pregnancy, under KV Pharmaceuticals dramatic increase the total cost for treatment per pregnancy could soar as high as \$30,000,” Saade further explained. “This financial barrier could discourage and lockout at-risk women, especially low income women, from receiving this life-saving injection. The FDA announcement will allow all women to continue to receive affordable treatment.”

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The Society for Maternal-Fetal Medicine (est. 1977) is a non-profit membership group for obstetricians/gynecologists who have additional formal education and training in maternal-fetal medicine. The society is devoted to reducing high-risk pregnancy complications by providing continuing education to its 2,000 members on the latest pregnancy assessment and treatment methods. It also serves as an advocate for improving public policy, and expanding research funding and opportunities for maternal-fetal medicine. The group hosts an annual scientific meeting in which new ideas and research in the area of maternal-fetal medicine are unveiled and discussed. For more information, visit www.smfm.org.

Editor's Note: The FDA statement is available on www.smfm.org in the SMFM Newsroom, or visit the FDA site at.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm>

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