



NEWS

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**CONTACT: Vicki Bendure, APR
540-687-3360 (o) /202-374-9259 (c)
Vicki@bendurepr.com**

SOCIETY FOR MATERNAL-FETAL MEDICINE STRONGLY OPPOSES SKYROCKETING INCREASE IN COST OF DRUG PROVEN TO PREVENT PRETERM LABOR IN HIGH-RISK PREGNANCIES

WASHINGTON, D.C., March 21, 2011 – The Society for Maternal-Fetal Medicine (SMFM) announced today strong opposition to KV Pharmaceutical’s recent pricing of its drug “Makena.” SMFM represents more than 2,000 physicians who have specialized training in maternal-fetal medicine and work with high-risk pregnancies where drugs such as Makena are often prescribed. The drug, designed to prevent preterm pregnancies is being sold at \$1,500 per dose. Makena, which has been produced as compound 17-hydroxyprogesterone by compounding pharmacies for several years, has typically cost \$10 to \$20 per dose.

“The research for this drug was funded by taxpayer dollars,” stated George Saade, M.D. president of SMFM. Tax dollars 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,” added Saade. 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.”

SMFM is actively engaged in efforts to maintain affordable access to the drug and is supporting Congressional efforts to investigate KV Pharmaceutical’s decision to increase the price of an existing and proven drug by 14,900%. A letter has also been sent to KV Pharmaceutical urging reevaluation of its pricing structure.

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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.

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