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South Carolina Medicaid to fight lawsuit filed by drugmaker; will continue to make “17P” available to expectant mothers who need it

COLUMBIA, S.C. — The South Carolina Department of Health and Human Services (SCDHHS) announced today it will vigorously defend itself against a lawsuit filed in federal court earlier this month by drug manufacturer K-V Pharmaceutical Co. K-V also filed separate suits against Georgia and the U.S. Food and Drug Administration.

At the center of the controversy is 17P, a hormone injection which helps prevent pre-term births. The use of compounded 17P is accepted by doctors as a safe and effective therapy to fight prematurity, and since 2005 SCDHHS has worked closely with physicians statewide to make it readily available to women at risk of pre-term births. SCDHHS, the March of Dimes, the SC Chapter of the American College of Obstetrics and Gynecology and the South Carolina Hospital Association are working together through the statewide Birth Outcomes Initiative to actively promote the use of 17P.

K-V contends that South Carolina, other states, and the federal government should be forced to buy their recently-approved branded version of 17P, branded as Makena®, at exorbitant prices and that physicians in South Carolina should be required to use it.

Physicians in South Carolina can currently request Makena® for their patients if it is medically necessary. Requests for Makena® go through a Prior Authorization (PA) process. The same type of process is used for hundreds of other drugs. To date, however, SCDHHS is not aware of a single PA request for Makena®. The compounded version of 17P continues to be widely prescribed by South Carolina physicians.

“We’ve been providing compounded 17P for years to women who need it and will continue to do so,” said SCDHHS Director Anthony Keck. “Forcing our physicians to use Makena® so K-V can meet its quarterly profit objectives is not an option for us.”

The lawsuit is seen as a last ditch effort by K-V to avoid bankruptcy after years of management problems. K-V recently disclosed that there is "the risk that the Company may be insolvent in the near term" due to

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a variety of factors including questionable ability to make more than \$100 million of interest payments and other payment obligations in the next several weeks; risks to company liquidity and assets associate with a 2008-2009 FDA suspension of production and a nationwide recall of all products K-V manufactured; and other reasons spelled out in company disclosures stemming from legal problems with patients, shareholders and the state and federal government.

“K-V apparently is trying to force taxpayers to bail out their management team after years of poor business decisions,” Keck said. “This is the perfect example why health care is so expensive in the United States - a pharmaceutical company that believes it should use lawyers to force doctors to prescribe a drug they don't want to use at a cost many times more than the current therapy that is working well to reduce prematurity.”

When K-V first launched its branded drug in March 2011, it listed Makena's® price at over \$1500 per injection — 75 times the cost of compounded 17P —a move which outraged physicians, pharmacists and states and birthing advocates nationwide. “I hope that the FDA, advocates and our sister states continue to stand strong against the political and legal pressure this company is bringing down on us all,” Keck said.

South Carolina is on the forefront of leading the fight against prematurity and infant mortality. The South Carolina Birth Outcomes Initiative is an effort by SCDHHS and its partners to improve the health of newborns in the Medicaid program. Launched in July 2011, the Birth Outcomes Initiative is focused on achieving five key goals: keeping 17P widely available to expectant mothers who need it; ending harmful elective inductions for non-medically indicated deliveries prior to 39 weeks; reducing the average length of stay in neonatal intensive care units and pediatric intensive care units; reducing health disparities among newborns; and implementing a universal screening and referral tool for physicians to help identify and treat tobacco use, substance abuse, depression and domestic violence among pregnant women.

The Department also recently announced financial incentives to expand “centering” programs that have had great success in Upstate South Carolina in reducing prematurity through group prenatal care, as well as additional funding for hospitals which become certified “baby friendly.”

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