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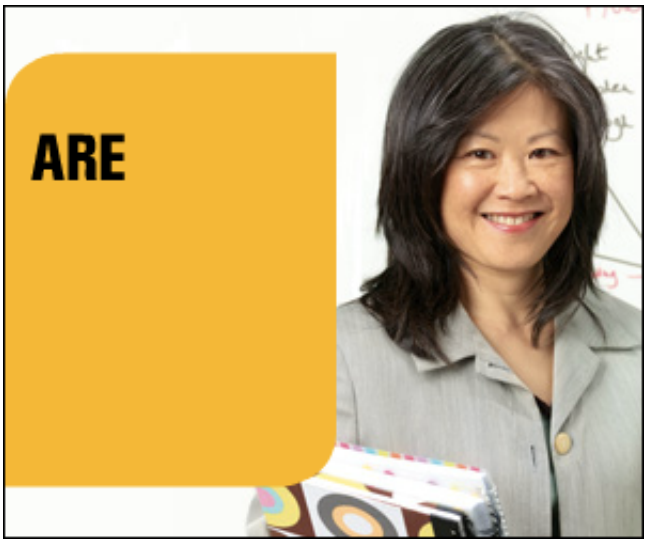
# FDA to allow cheaper preterm baby drug




**By Rob Stein, Published: March 30, 2011**

The Food and Drug Administration on Wednesday took the unusual step of announcing that it would allow pharmacies to continue to produce less expensive versions of a drug long used to reduce the risk that women will give birth prematurely.

The move was aimed at defusing a controversy that erupted after the agency approved the drug Makena to prevent preterm births. Makena's owner, KV Pharmaceutical of St. Louis, is charging $1,500 a dose for the drug. The same compound had been available for years for about $10 to $20 a dose.

The FDA's statement came a day after The Washington Post reported the intense criticism that has arisen over Makena. After word of Makena's price began to spread, Internet sites for pregnant women became filled with angry commentary. Some created Facebook pages lambasting KV. The price also drew harsh criticism from several members of Congress, as well as many doctors and medical groups, including the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

On Wednesday, the FDA challenged KV's warning to specialty pharmacies that had been producing the cheaper versions of the drug that the agency would no longer permit that.

"This is not correct," FDA spokeswoman Beth Martino said in an e-mailed statement that was later posted on the agency's Web site.

Although the agency usually does not recommend patients use compounded versions of FDA-approved drugs, "in order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound" the agent, the statement said.

The agency will only step in if "the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products," according to the statement. "As always, FDA may at any time revisit a decision to exercise enforcement discretion."

The FDA's announcement was praised by advocates for pregnant women.

"This is wonderful news and a victory for preemie families that have suffered significant amounts of trauma, more than most people can understand," said Mary Beth Hazelgrove, executive director of the

group Preemies Today.

Added George Saade of the Society for Maternal-Fetal Medicine: “This action will ensure that this lifesaving 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.”

Several members of Congress who had protested the price also praised the decision.

“FDA’s announcement is a victory for pregnant women, consumers and taxpayers,” said Sen. Sherrod Brown (D-Ohio).

More than 500,000 of the 4.2 million women who have babies each year give birth prematurely, and many of the babies don’t survive. Those who do are at increased risk for many health problems, including mental retardation, cerebral palsy and autism.

A form of the hormone progesterone, known as 17P, for years had been used to reduce the risk of preterm birth. But the drug fell out of favor after the manufacturing company stopped making it. In 2003, a National Institutes of Health study showed that 17P could cut the risk of preterm delivery if given in the first 16 to 24 weeks of pregnancy. That led to a resurgence in its use. Because no companies marketed the drug, women obtained it cheaply from compounding pharmacies, which produce individual batches of drugs for patients.

But doctors and regulators had long worried about the purity and consistency of the compounded drug and were pleased when KV won FDA’s imprimatur for a well-studied version, which the company is selling as Makena.

The approval of Makena in February gave the company seven years of exclusive rights, and KV immediately fired off letters to compounding pharmacies, warning that they could no longer sell their versions of drug.

Because the drug must be given for about 20 weeks, Makena would cost about $30,000 for each at-risk pregnancy, which could add more than $4 billion to the nation’s health-care bill.

KV has defended Makena’s price, saying the company had spent more than $200 million to develop the drug, which saved an estimated $50,000 for every preterm birth avoided. In addition, KV had started a program to help women who cannot afford the drug, the company said.

In a statement Wednesday, the company said it “takes very seriously the public concerns raised” about the price and would announce “solutions” by the end of the week.

“It is our commitment that every woman who is prescribed Makena will have affordable access to this FDA-approved and FDA-monitored therapy,” the company said.

KV’s stock price fell more than 20 percent Wednesday.