

FDA won't stop cheap version of preterm birth drug

March 30 2011, By MIKE STOBBE , AP Medical Writer

(AP) -- Pregnant women will still be able to get a drastically cheaper version of a new expensive drug that prevents premature birth, federal health officials said Wednesday.

Since the drug was approved, it's been unclear whether women would have to pay \$1,500 per dose for the licensed version or could continue to have it made by specialty pharmacies for \$10 to \$20.

The price increase caused an outcry, and the Food and Drug Administration on Wednesday took the unusual step of declaring that pharmacies can still make the cheap version of the once-a-week shot on an individual basis, as they have for years. The agency said it wouldn't step in unless there was a problem with the safety of the specially made version.

In response, KV Pharmaceutical Co, which makes the drug named Makena (mah-KEE'-nah) said it was committed to making sure all women who need the drug have access to it. The company said it plans another announcement by the end of the week about the drug's price.

The drug helps prevent premature births in women who previously delivered early.

Doctors and others had welcomed the FDA approval of the drug last February, but were stunned when the \$1,500 per dose price was announced. Total cost during a pregnancy could be as much as \$30,000.

The FDA does not control pharmaceutical pricing. The company said the price was justified because the drug can prevent premature births that can result in mental and physical disabilities, and because it spent millions bringing the drug to market.

Last month, the company sent a letter to special pharmacies across the country, warning them to stop making the cheaper version or they would face FDA enforcement. An FDA spokeswoman initially said the company's letter was accurate. But on Wednesday, the FDA stated that wasn't right.

The FDA has become increasingly aware of public worry and anger over whether women would still be able to get the drug, and whether government Medicaid programs that serve the poor would still be able to pay for it, federal officials said.

"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 drug, a form of progesterone also known as 17P, the statement said.

The FDA's action was applauded by the March of Dimes, which initially had a muted reaction to Makena's cost but has become more forceful in calling for a price reduction. The announcement "lays to rest any ambiguities about whether specialty pharmacies can continue to compound 17P. It would be a tragedy to interrupt access to this important drug," a statement from the group said.

"FDA's announcement is a victory for pregnant women, consumers, and taxpayers," said U.S. Sen. Sherrod Brown, an Ohio Democrat who has called for a federal investigation into Makena's pricing.

Experts say the Makena situation is unusual. More commonly,

pharmaceutical companies develop a new drug and - after it comes on the market - some pharmacies may try to make a version of the licensed drug. But in this instance, pharmacies were making it before KV.

What's more, the FDA's regulation of special pharmacies is "a gray area" based on agency policies, not laws, noted Alvin J. Lorman, a respected Washington, D.C.-based food and drug lawyer.

KV, based in suburban St. Louis, previously announced a patient assistance program that would discount the price for women who met certain guidelines. The company said Wednesday it was "exploring additional ways to help provide affordable access for all patients who are prescribed Makena."

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