

Price slashed for drug to prevent preemie births

April 1 2011, By MIKE STOBBE , AP Medical Writer

(AP) -- The maker of an expensive drug to prevent premature births slashed the price by more than half on Friday, following an outcry over the high cost and moves by federal regulators to keep a cheap version available.

The drug is still pricey at \$690 per weekly injection but it is a drastic reduction from the \$1,500 price charged by KV Pharmaceutical Co. when it went on the market last month. The company also announced rebates and other steps to give the drug to needy pregnant women at little or no cost.

The price cut came two days after federal officials said they would not stop specialty pharmacies from continuing to make a generic version that sells for \$10 to \$20 a dose, as has been done for years.

The company got government approval in February to exclusively sell the drug named Makena (mah-KEE'-nah). But the price stunned doctors who prescribe the drug and private and public insurance plans, including state Medicaid programs, that pay for it. The drug is given to high-risk pregnant women to avoid another early birth.

The pricing controversy exploded after The Associated Press reported on the issue early last month, with some members of Congress calling for a federal investigation.

The Food and Drug Administration, which has no say in drug pricing,

took the unusual step of announcing that the special pharmacies could still make the cheap version for individual patients if doctors prescribe it. Typically, those pharmacies aren't supposed to make versions of licensed drugs, and KV Pharmaceutical had warned them to stop making the preterm birth drug or face enforcement by the FDA.

But on Wednesday, the FDA said that "to support access to this important drug, at this time and under this unique situation," it would not take action against pharmacies that make the drug.

The agency acted because of the public worries that women won't be able to afford the drug, federal officials said.

The suburban St. Louis-based KV Pharmaceutical had earlier defended its pricing, saying the company is spending a quarter of a billion dollars on the drug's development, including \$60 million in research.

Chief executive Gregory J. Divis Jr. had said the \$1,500 price was justified to avoid the mental and physical disabilities that can result from very premature births. Premie care can cost an estimated \$51,000 in the first year alone, he said.

KV Pharmaceutical officials were not available for an interview on Friday, said a company spokeswoman.

In a statement, Divis acknowledged that prospective buyers of the drug were not happy. He said company officials were cutting the price because they want to make sure all women can get the drug, noting the "budget challenges facing state Medicaid programs and other payers."

The weekly injection is given for as long as 20 weeks; the price drop cuts the maximum cost of treatment from \$30,000 to under \$14,000.

KV had earlier announced a patient assistance program to provide the drug to uninsured and low-income women. On Friday, the company announced an expansion of that program, lifting income limits so most women would pay less than \$20 per injection. It also offered to cap costs for state Medicaid agencies and health insurance plans.

"They had to respond, they had to bring the price down, because people were so outraged," said Dr. Kathryn Menard, a University of North Carolina specialist who oversees a state program that has been providing the cheap version of the drug to women at risk for preterm births.

She added that \$690 is still pricey, and many obstetricians may prescribe the compounded version.

Sen. Sherrod Brown, D-Ohio, an early and persistent critic of the original price, called the cut "a small step in the right direction," but said "KV Pharmaceutical is still putting profit over patients."

The company benefited from nearly \$21 million in taxpayer money that was spent on early research on the drug, he noted in a statement.

The drug is a synthetic form of the hormone progesterone. It came on the market more than 50 years ago to treat other problems and was withdrawn in the 1990s, though not for safety reasons.

But the drug got a new life in 2003, with publication of a study that reported it helped prevent early births to women who had a history of giving birth prematurely. Obstetricians began prescribing the drug for more women, but it was only available through "compounding" pharmacies.

Initially, doctors were glad to hear that KV Pharmaceutical was licensing the drug. It meant it would be manufactured in an FDA-regulated

facility, with tighter controls and follow-up testing to ensure quality and consistency from dose to dose.

But doctors also say there have been no reported problems with the safety or quality of the cheap version. So for many obstetricians, the perks of having an FDA-approved drug may not make up for its still-high price, Menard said.

Also Friday, the March of Dimes issued a statement announcing it was severing all professional ties with the KV subsidiary that is marketing Makena.

The advocacy group was getting hundreds of thousands of dollars from the subsidiary, Ther-Rx. The March of Dimes had celebrated the FDA approval of the drug back in February, and was at first muted in its criticism of Makena's price.

The organization, which heavily relies on volunteers for fundraising and other activities, came under fire from some of its supporters. In recent weeks, March of Dimes officials pushed for a price cut.

"They trusted this company, and any bit of (financial) support they got from the company is not worth what they're going to lose by continuing a relationship with them," said Menard, who is president-elect of the Society for Maternal-Fetal Medicine.

In a statement, KV called the March of Dimes decision "disappointing."

More information: FDA statement: <http://tinyurl.com/fdastatement>

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