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FOLLOWING BROWN INTERVENTION, FDA WILL ALLOW CONTINUED PRODUCTION OF AFFORDABLE VERSION OF PRE-TERM PREGNANCY DRUG

In Response to Hearing Question from U.S. Sen. Sherrod Brown, New Announcement from FDA Will Allow Safe Version of Pre-Term Labor Drug to Continue to be Produced by Compounding Pharmacists
Brown Questioned Head of HHS on KV Pharmaceuticals – Which Increased Price of Existing Drug from $10 per Dose to $1,500 per Dose

WASHINGTON, D.C. – In response to a question posed by U.S. Sen. Sherrod Brown (D-OH) at a hearing today with the Secretary of Health and Human Services, the Food and Drug Administration (FDA) announced that it will allow for the continued production of a pre-term pregnancy drug – known as 17P – that has been safely produced by compounding pharmacists for years. Earlier this month, KV Pharmaceuticals acquired exclusive rights to sell 17P - which it will market as Makena - for seven years. The company later increased the price per dose from $10 to $1,500 and began sending a cease-and-desist order to prevent the manufacture of other progesterone treatments used to prevent pre-term pregnancies.

"FDA's announcement is a victory for pregnant women, consumers, and taxpayers," **Brown** said. "This drug, which was developed with extensive taxpayer support, is too important to fall out of reach for pregnant women."

"I applaud FDA's action to ensure that the safe and affordable version of this drug remains available. However, FDA never should have had to take this action in the first place," **Brown continued. "**FDA approval of a drug should not mean a 15,000% percent increase in the price of a drug – especially when the drug company received significant assistance from taxpayers in developing the product, including research funded by NIH. FDA's decision to allow the affordable version of this drug to remain on the market is important for women and children, but I remain very upset that KV Pharmaceuticals has acted in such an irresponsible way as to force this action."

A Timeline of Congressional Actions
After KV announced that the drug used to prevent pregnant women from delivering premature babies would increase from $10 per dose to $1,500 per dose, Brown was the first Member of Congress to take action - sending a letter to the CEO of KV Pharmaceuticals on March 10 urging the company to reverse course on the price hike. A week later, on March 17, he sent a letter requesting an antitrust investigation of KV's practices by the Federal Trade Commission (FTC). On March 25, Brown called for a federal investigation on the effect of the price hike on taxpayers and the Medicaid program.

Background
Taxpayer dollars actually helped finance the research and development of this product. Tax dollars funded the first clinical trial in 2003 through the National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health (NIH), as well as subsequent trials in the years following.

KV Pharmaceuticals paid $200 million to acquire exclusive rights to sell the progesterone treatment – which it will market as Makena – for seven years. With FDA approval in hand, KV began sending a cease-and-desist letter to pharmacies to prevent them from selling the drug. Last week, KV announced it would sell Makena for $1,500 per dose -- an estimated $30,000 per pregnancy.

The company justified this price hike by citing R&D costs, and even implied that the more expensive treatment is still below the costs associated with a premature birth. At $1,500 per dose, KV could recoup its $200 million investment 18 times in the first year – netting a $3.7 billion profit. This price increase could lead to fewer women being able to afford the drug, increasing our nation's already too-high preterm birth rate of 13 percent. Higher costs mean that health insurance companies could either stop coverage of the treatment or impose higher premiums on consumers and already stretched state Medicaid programs would be forced to deal with the financial repercussions of the company's decision.

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