

For Immediate Release
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BROWN URGES SENATE COMMITTEE HEARING ON OUTRAGEOUS RATE HIKE FOR DRUG THAT PREVENTS PRE-TERM LABOR

Brown Asks HELP Committee Chairman to Hold Senate Hearing to Investigate 14,900 Percent Increase

WASHINGTON, D.C. – After pressing Health and Human Services Secretary (HHS) Kathleen Sebelius on the outrageous price increase of a critical drug used to prevent pregnant women from delivering premature babies, U.S. Sen. Sherrod Brown (D-OH) urged Health, Education, Labor, and Pensions (HELP) Chairman Tom Harkin to hold a senate hearing investigating the 14,900 percent increase in dosage cost from \$10 per dose to \$1,500 per dose.

“The diagnosis of a complicated pregnancy is worrisome enough. This anxiety shouldn’t be heightened by the worry of how to pay for a once-affordable treatment,” Brown said. “Since KV Pharmaceuticals announced the intended price hike, I called on KV Pharmaceuticals to immediately reconsider their decision, but to this date the company continues to defend this astronomical price increase. Price-gouging is never acceptable, particularly not when it undermines public health and fleeces taxpayers. Parents-to-be deserve an investigation.””

At the press conference, Brown called for an investigation by the Federal Trade Commission (FTC) to determine if the actions of KV – which has been sending cease and desist letters to pharmacies that sell a different, compounded version of the drug – violate antitrust rules.

Brown [sent a letter to the CEO of KV Pharmaceuticals](#) urging the company to reverse course on the price hike, and earlier this month, [he sent a letter requesting an antitrust investigation](#) of KV’s practices by the Federal Trade Commission (FTC).

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 sent 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.

March 25, 2011

*Senator Tom Harkin
Chairman
Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510*

Dear Chairman Harkin:

As you know, KV Pharmaceuticals recently obtained exclusive rights to Makena, a newly approved drug used to prevent pre-term births. A version of this drug – a progesterone treatment widely available through compounding pharmacies – has been used for years with significantly improved outcomes for high-risk women.

Taxpayer dollars 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, as well as subsequent trials.

Upon securing market exclusivity for this treatment, KV Pharmaceuticals sent a cease and desist letter to compounding pharmacists and announced that it would increase the price per dose from about \$10 to \$1,500, meaning the course of treatment for pregnant women would cost \$30,000.

This is an outrage. I/We have asked the company to reconsider its decision, as have a number of health provider groups. I/We hope the company will decide quickly to set a price providing a fair return on its investment without pricing this product beyond the reach of expectant mothers.

I/We understand the importance of the FDA approval process in ensuring that medications are safe and effective. But KV is taking advantage of FDA's approval and its orphan drug determination to make enormous profits on the backs of pregnant women, taxpayers, businesses, and the public and private health care systems.

If the company does not reconsider quickly, I/we respectfully urge you to hold a hearing before the Committee on Health, Education, Labor, and Pensions to investigate KV Pharmaceutical's proposed 14,900 percent price increase on a proven treatment to prevent premature births, and what Congress and the Administration might do to provide a more reasonable alternative.

In advance, thank you for your consideration of our request.

Sincerely,

SB et al