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IN WAKE OF PRICE HIKE FROM \$10 PER DOSE TO \$1,500 PER DOSE FOR DRUG THAT PREVENTS PRE-TERM LABOR, BROWN JOINS OBSTETRICIANS AND MOTHER-TO-BE TO CALL ON COMPANY TO RETHINK DECISION

At News Conference, Brown Calls for Investigation on Effect of Price Hike on Taxpayers and Medicaid Program
Brown Has Called for Federal Trade Commission Antitrust Investigation of KV Pharmaceuticals – Which Increased Price of Existing Drug from \$10-20 per Dose to \$1,500 per Dose

YOUNGSTOWN, OH – Starting this month, the price of a critical drug used to prevent pregnant women from delivering premature babies increased from \$10-20 per dose to \$1,500 per dose. U.S. Sen. Sherrod Brown (D-OH) today joined Drs. Nick Kreatsoulas and Oscar Khawli, along with a mother-to-be, at St. Elizabeth Health Center to call on KV Pharmaceutical to reverse course on the outrageous price increases of a drug to prevent preterm pregnancy. At the news conference, Brown called for a federal investigation on the effect of the price hike on taxpayers and the Medicaid program.

“Price-gouging is never acceptable, particularly not when it undermines public health and fleeces taxpayers. Parents-to-be—and taxpayers—deserve answers,” Brown said. “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. 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.”

At the news conference, Brown [released a letter he is sending \(http://brown.senate.gov/imo/media/doc/SB_MakenaLettertoCMS.pdf\)](http://brown.senate.gov/imo/media/doc/SB_MakenaLettertoCMS.pdf) to the director of the Centers for Medicare and Medicaid Services (CMS) requesting that the agency investigate the ramifications of KV Pharmaceutical’s 150-fold price increase of Makena. In the letter, Brown expresses his concern about the strain this dramatic price increase will place on Medicaid budgets across the country. According to the American College of Obstetricians and Gynecologists (ACOG), Medicaid helps finance 42 percent of the nation’s more than 4 million annual births.

“As approximately 12 percent of all live births involve a preterm baby, I am deeply concerned that the expense of Makena will further burden Medicaid budgets which are already stretched thin,” Brown wrote to CMS Director Dr. Donald Berwick. “While I understand the importance of FDA-approved drugs to ensure that medications are safe and effective, KV is taking advantage of FDA’s approval of Makena and its orphan drug determination to make enormous profits on the backs of pregnant women, taxpayers, and the Medicaid system.”

Brown has 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. The drug for high-risk pregnant women, which KV Pharmaceutical plans to sell under the brand name Makena, has been produced by compounding pharmacies for years and typically costs between \$10-20. Last month, KV Pharmaceutical became the first company to receive FDA approval to sell the product and plans to raise the cost to \$1,500 per dosage.

Brown [sent a letter to the CEO of KV Pharmaceuticals](http://brown.senate.gov/newsroom/press_releases/release/?id=eb142edd-068f-43b8-b6a0-e7250ae78281) (http://brown.senate.gov/newsroom/press_releases/release/?id=eb142edd-068f-43b8-b6a0-e7250ae78281) urging the company to reverse course on the price hike, and last week, [he sent a letter requesting an antitrust investigation](http://brown.senate.gov/newsroom/press_releases/release/?id=ba4fee2d-7d8e-40a5-86b1-74610cf1cb02) (http://brown.senate.gov/newsroom/press_releases/release/?id=ba4fee2d-7d8e-40a5-86b1-74610cf1cb02) 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.

Preterm birth affects 1 in 8 babies, and is responsible for serious complications, including infant death. Among survivors, infants delivering preterm are at increased risk of suffering serious long-term complications, including delays in development, cerebral palsy, hearing and vision problems, and chronic lung disease.

Higher costs of a drug like Makena mean that health insurance companies could either stop coverage of the treatment or impose higher premiums on consumers, and those who are uninsured could have limited access to the treatment. Already stretched state Medicaid programs would be forced to deal with the financial repercussions of the company's decision unless pricing is changed or less expensive compounded alternatives remain available.

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