Brown Statement on Makena Repricing
In Wake of Price Adjustment, Brown Releases New Figures Showing Scope of Taxpayer Investment in Preterm Labor Drug's Research and Development

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WASHINGTON, D.C. – U.S. Sen. Sherrod Brown (D-OH) released the following statement today after KV Pharmaceutical, the manufacturer of a drug to prevent pre-term labor in high-risk pregnant woman, announced its decision to lower the price of its injection to $690 per dose from $1,500 per dose. Brown today released new figures showing the scope of taxpayer investment in the drug's research and development.

"Today may be April Fool's Day, but KV Pharmaceutical's decision to reduce the list price of its drug to nearly $700 per dose is no laughing matter," Brown said. "Even with the new price, a full course of treatment of Makena will still cost more than $10,000. KV's announcement is a small step in the right direction, but I remain extremely concerned about the enormous strain this drug will place on Medicaid budgets and patients with private health insurance.

"With the FDA's decision to continue allowing compounding pharmacies to manufacture 17P, I'm optimistic that the majority of women will still have access to an affordable version of this critical, life-saving injection. But it shouldn't have to take Congressional outrage and a spate of negative news stories for a company like KV Pharmaceutical to do the right thing. With more than $20 million of taxpayer dollars invested in Makena's research, and with thousands of babies at risk, KV Pharmaceutical is still putting profit over patients," Brown continued.

Until KV Pharmaceutical acquired exclusive rights to manufacture the drug, also known as 17P, compound pharmacies sold the injection for $10-$20 per dose. At 20 weeks of treatment, KV Pharmaceutical's decision effectively raised the total cost of treatment from $200-$400 to $30,000. The company's repricing decision today would still cost a high-risk pregnant woman more than $10,000 for a full course of treatment.

NIH Research, Funded with Taxpayer Dollars, Helped Bring Makena to Market

In wake of KV's announcement today, Brown released previously-unreported figures showing the scope of taxpayer investment in the development of pre-term pregnancy drugs. In total, taxpayers have invested nearly $21 million, through research conducted by the National Institutes of Health (NIH) to bring Makena to market.

An initial trial, showing that the injection prevented preterm births in women who have previously had a preterm birth, cost taxpayers $5 million.

A second trial, at $1.1 million, showed no side effects in children whose mothers had used the formulation.

A third trial, costing taxpayers $5.1 million, found that the drug did not work to prevent preterm birth in women carrying twins and triplets; according to the NIH, this study was critical for Makena's orphan drug status determination because an alternative result could have widened the number of potentially eligible women to use the drug.

A fourth trial, which is still ongoing, cost $7.5 million through Fiscal Year 2010 and aims to find whether 17P treatments are effective at preventing preterm birth in women with shortened cervixes. This is the largest study of 17P by the NIH, and could create another category of women eligible for Makena.

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. Recently, 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.