

United States Senate

WASHINGTON, DC 20510

March 10, 2011

Greg Divis
Chief Executive Officer
KV Pharmaceutical Company
President
Ther-Rx Corporation
One Corporate Woods Drive
Bridgeton, MO 63044

Dear Mr. Divis:

According to reports in the Associated Press, your company plans to impose a massive price increase on a drug that, for years, has worked to prevent preterm labor in high-risk pregnant women. Not only will this price hike be overly burdensome on state Medicaid programs and health insurance companies, it will invariably result in reduced access and, as a result, more premature births.

For years, this progesterone treatment, which you plan to sell under the brand name Makena, has been produced by compounding pharmacies. Last month, KV Pharmaceutical became the first company to receive FDA approval to sell this product. While I understand and commend the Food and Drug Administration (FDA) for their efforts to ensure that drugs marketed and sold in the United States are safe and effective, I am deeply concerned that your company appears to be taking advantage of FDA approval at the expense of women, children, and federal and state budgets.

Prior to your company receiving FDA approval, this important drug had been available to women at a cost of \$10-20 per injection. Reports indicate that, next week, you plan to raise the price to \$1,500 per shot. This represents an increase of up to 14,900 percent. The drug industry attributes the high price tag of the brand name medicines it sells in the United States to the cost of research and development (R&D). Since it is likely that the only material R&D costs your company incurred in order to receive approval of this drug were those associated with conducting clinical trials, it is disturbing that you have chosen to inflate its price so dramatically.

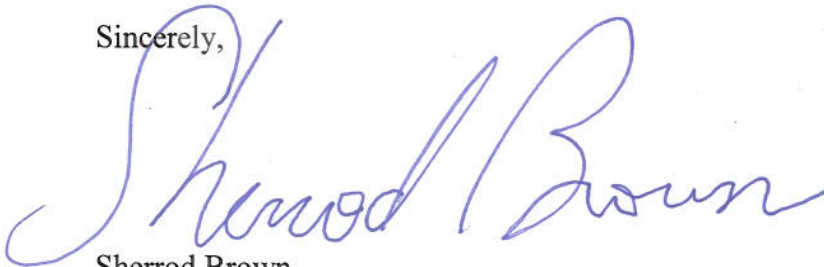
According to the March of Dimes, nearly 13 percent of babies in the United States are born prematurely – more than half a million a year. In yet another example of unacceptable health disparities in our nation, non-Hispanic black women have a higher proportion of preterm births than Hispanics and non-Hispanic whites. Babies born prematurely face increased risks of lung problems, hearing and vision loss, cerebral palsy, and other learning and behavioral health problems. In addition to the health concerns related to preterm births, the financial cost to our nation is significant. For instance, Nationwide Children's Hospital reports that Neonatal

Intensive Care Unit (NICU) stays average \$66,000 in Franklin County, Ohio and can cost in excess of \$2 million. In 2006, the Institute of Medicine found that preterm births cost the United States at least \$26 billion annually.

I am gravely concerned that the exorbitant price increase your company plans to implement next week will increase rates of preterm birth nationwide. Fewer women will be able to afford the drug, health insurance companies could either stop coverage of the treatment or impose higher premiums on consumers, and state Medicaid programs – which are already struggling to make ends meet – will be forced to deal with the financial repercussions of your company's decision.

I ask that you immediately reconsider this massive price increase.

Sincerely,

A handwritten signature in blue ink that reads "Sherrod Brown". The signature is written in a cursive, flowing style.

Sherrod Brown
United States Senator