

Compounded medication to prevent preterm birth not a safety risk, pitt study confirms

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(Medical Xpress)—A new study published online today in the *American Journal of Obstetrics and Gynecology* by researchers from the University of Pittsburgh School of Medicine and the University of Pittsburgh School of Pharmacy reports that 17-hydroxyprogesterone caproate (17-OHPC), a medication that reduces the rate of preterm birth in high-risk women, did not raise any safety concerns when the medication was prepared and dispensed by independent compounding pharmacies throughout the United States.

17-OHPC has been proven to reduce the risk of preterm births in women with a clinical history of early delivery by one-third. Until recently, this medication was available only from independent compounding pharmacies with a cost of \$10 to \$15 per injection. A pharmaceutical company in February 2011 received FDA approval to license the medication under the name Makena and established the price at \$1500 per injection. The public outcry that followed led the FDA to issue a statement that it would not enforce action against compounding pharmacies that continued to produce and provide the medication.

Since then, researchers from the company that markets Makena, published a report suggesting compounded 17-OHPC poses a risk to patients because of the potential for drug impurity and inconsistent potency. The FDA conducted its own study and could not identify any safety problems with the drug, but decided it would apply its normal enforcement policy on compounding the product.

Researchers from Pitt's School of Medicine and School of Pharmacy conducted an independent study to determine the quality of 17-OHPC obtained from compounding pharmacies across the country. Specialists in treating high-risk pregnancy supplied a representative sample of the compounded 17-OHPC used in their practices. Eighteen samples of compounded 17-OHPC were obtained from 15 pharmacies and analyzed at Pitt.

"Contrary to the report provided by the company that markets Makena, we found that 17-OHPC from compounding pharmacies raised no safety concerns about drug potency, sterility or purity," said Steve N. Caritis, M.D., professor of obstetrics and gynecology at Pitt, and the study's corresponding author. Dr. Caritis cautioned, however, that the sample size was small and the findings cannot be applied to all compounded products or pharmacies.

"If a compounding pharmacy is used for preparation of 17-OHPC, a discussion with the [pharmacy](#) preparing the product is prudent, to assure production of a high-quality product," Dr. Caritis said.

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Provided by University of Pittsburgh

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