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Late last month, a little-noticed struggle at the U.S. Food and Drug Administration (FDA) provided a glimpse into the perpetual fight for affordable, quality health care.

Last February, the FDA approved a new drug called "Makena" which was touted as a breakthrough treatment for preventing preterm births for women with at-risk pregnancies. The value of a viable treatment option for preventing preterm births is clear not only for families, but also for America's public health system. More than 500,000 babies are born prematurely in the U.S. every year, and the resultant medical care costs roughly \$29 billion annually.

Having a treatment option that reduces the incidence of preterm births is a benefit to expectant parents, and an intelligent, preventive strategy for controlling health care spending. Unfortunately, there's one problem with Makena: its cost. Makena was initially pegged at [\\$1,500](#) per treatment or \$30,000 per pregnancy. Since the FDA initially indicated that Makena injections would be the exclusive vehicle to administer hydroxyprogesterone medication, doctors and patients were left with little to cheer about, particularly because Makena was not an exclusive, new, innovative product. In fact, equivalent medication from compounding pharmacists has been available for decades.

"Compounded" versions of Makena (hydroxyprogesterone caproate) have been in use since the 1980's to help reduce the risk of preterm births at only \$20 per dose or \$400 per pregnancy. Over the years, the National Institutes of Health (NIH) has conducted studies on safety and

effectiveness of the compounded medication and the FDA's MedWatch has not documented a single health safety or consumer complaint. The treatment has proven a safe, effective, and accessible option for at-risk expectant mothers and the providers who care for them. Although the injectable version may in some instances provide valuable therapeutic results, the FDA's initial order left question as to whether the \$20 option would still be accessible. If at-risk expectant mothers were limited to the \$1500 per-dose option, many patients could not afford to be treated, thus increasing preterm births across the nation.

After the FDA order, the manufacturer of Makena, KV Pharmaceuticals, sent [threatening letters](#) to pharmacies around the country. The letters contained warnings that pharmacists continued use of compounded formulas of their newly-minted Makena would trigger enforcement action from the FDA. These letters, combined with KV's announcement that Makena would cost \$1,500, ignited a firestorm of complaints from obstetricians, patients, employers, and public officials. The latter group (Why not all were incensed?) was incensed at the huge increase in health care spending that an exclusive arrangement for hydroxyprogesterone would create.

Fortunately, the FDA announced last month that enforcement action would not be taken against pharmacists who continue to fill prescriptions with compounded versions of the medication. The FDA's announcement is a victory for patients and should serve as commonsense framework for other cost savings in our systems of care. While the FDA's decision was well received, I spearheaded a letter to FDA Commissioner Dr. Margaret Hamburg applauding his move, and vowing to monitor its adherence.

The impact of Makena's price tag would have rippled through our health care system. It would have impacted those without coverage in need of this treatment, including mothers and their babies. It would have increased premiums for those with coverage through cost shifting. And it would have exploded costs for state Medicaid programs, and in turn, the taxpayers who fund the system. The FDA needs to remain steadfast in their decision even in light of the announcement of Makena's lower price tag, which still may be cost prohibitive. Failing to do so would be a disservice to patients, to maternal and child health, and to the collective goal of reducing rising health care costs.

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