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Politics, Policy & Law

KV at the brink

By Steve Usdin
Washington Editor

After a week of unremitting and unprecedented pressure from **FDA, CMS, Congress, medical societies** and the public, it isn't clear whether **KV Pharmaceutical Co.** will be able to market its pregnancy drug Makena at a price that makes the company financially viable.

The company announced last Friday it had slashed the list price by 54% to \$690 per dose, and implemented new cost caps and patient assistance measures, but the moves did little to quell the anger.

Critically for KV, there is no sign FDA will back off from its decision to allow compounding pharmacies to continue selling inexpensive versions of the drug, a synthetic caproate ester of naturally occurring 17 alpha-hydroxyprogesterone (17P), which is widely used to prevent pre-term births.

FDA's enforcement of a ban on compounding hydroxyprogesterone caproate is a prerequisite for KV to obtain a premium price for Makena, as physicians and payers told BioCentury they are unlikely to use or reimburse for a premium-priced product if cheaper compounded alternatives are available.

Convincing patients

In addition to lowering the list price from \$1,500 per injection, KV on Friday said it was removing income caps on its patient assistance program. As a result, according to the company, "85 percent of patients will pay \$20 or less per injection for FDA-approved Makena, and patients whose financial need is greatest would receive FDA-approved Makena at no out-of-pocket cost."

KV made two arguments to justify its pricing of Makena: value to the healthcare system and the benefits of an FDA-approved product over compounded products.

"The use of Makena by eligible pa-

"I've often been critical of drug companies, but I've never seen something with this kind of over-reach, with this kind of greed."

Sen. Sherrod Brown, D-Ohio,
on *BioCentury This Week*

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tients will deliver net cost savings to Medicaid programs and private insurance plans in year one, based on third-party economic modeling of costs associated" with prematurity, the company said.

According to KV, the average medical cost of a premature baby's first year of life is \$51,000.

Moreover, CEO Greg Divis stated that "ensuring access to an FDA-approved sterile, injectable medication, manufactured under mandatory strict quality controls, is in the best interests of all high-risk women."

KV's decision to hit the reset button came after its initial pricing — \$1,500 per dose adds up to \$30,000 for a course of treatment — provoked outrage among physicians and patients who have had access to hydroxyprogesterone caproate from compounding pharmacies for a decade at prices from \$10-\$20 per dose (see *BioCentury, March 28*).

Events moved fast last week.

On Tuesday, Sen. Sherrod Brown (D-Ohio) cited the spread between the compounded cost and KV's list price for Makena when he told *BioCentury This Week*, BioCentury's public affairs television program, that the company's actions were "morally reprehensible."

Brown also said KV is an outlier. "I've often been critical of drug companies, but I've never seen something with this kind of over-reach, with this kind of greed."

Brown warned he was considering legislation to carve out

an exception from the provisions of the Food, Drug & Cosmetic Act that prohibit compounding pharmacies from selling FDA-approved drugs.

Several other members of Congress excoriated KV's pricing, as did the **March of Dimes**, one of the most prominent non-profit advocacy organizations focused on preventing premature births, and several medical organizations representing obstetricians.

In an SEC 10-Q filing last Thursday,

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"The use of Makena by eligible patients will deliver net cost savings to Medicaid programs and private insurance plans in year one."

KV Pharmaceutical statement

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KV disclosed that Senate Finance Committee staff warned the company that “federal legislation targeted at the company’s sale of Makena may be introduced unless the company reduces its price.”

It added: “Communications with members of Congress and their staffs indicate that hearings in Congress on the company’s pricing of Makena may occur.”

The day before, on Wednesday, FDA announced that it “does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products.”

FDA said it made the announcement in “order to support access to this important drug, at this time and under this unique situation.”

The agency did not describe the “unique situation,” but the decision was reached after several members of Congress contacted Commissioner Margaret Hamburg asking her to make a public statement indicating that FDA would not prevent compounding of hydroxyprogesterone.

In the absence of FDA’s announcement, pharmacies would have stopped producing the product, according to Marcy Bliss, EVP for business operations, marketing & sales at **Wedgewood Pharmacy**, which is one of the nation’s largest compounding pharmacies.

Wedgewood “has dispensed tens of thousands of doses of 17P since 2003” when an NIH study demonstrated the safety and efficacy of hydroxyprogesterone to prevent pre-term birth, Bliss told BioCentury.

Bliss said Wedgewood sells the product for \$12.60 per dose, principally in 10-dose vials. “Almost all of the cost is labor, the active ingredient costs very little,” she added.

FDA’s announcement set the stage for CMS to inform state Medicaid programs that they can choose to pay for compounded 17P.

According to KV’s 10-Q, CMS’s action “has the potential of excluding Makena from being provided under the various state Medicaid programs,” and that “Medicaid programs cover approximately 40% to 45% of the total number of pregnancies in the United States.”

Not enough

It would take an enormous price drop to wean Medicaid from compounded versions of hydroxyprogesterone, according to Matt Salo, director of the **National Association of State Medicaid Directors**.

The Makena “price drop was necessary, but not sufficient. Going from \$10 [for the compounded drug] to \$1,500 was ludicrous and offensive; going from \$10 to \$700 or even \$400 is less so, but still unaffordable,” Salo told BioCentury.

Indeed, he said, “any price over \$10 is problematic for Medicaid in this budget environment. States are trying to close a collective \$175 billion budget gap and every Medicaid program is going to be making broad, deep cuts anywhere it can.”

Even with the price cut, Makena would cost Medicaid more than \$400 million a year more than compounded hydroxyprogesterone (see “Makena by the Numbers,” A25).

Physicians are also not clamoring for an FDA-approved product.

“Practicing obstetricians, gynecologists and high-risk obstetricians have been very comfortable using this compounded medication to provide this needed therapy to their patients,” Hal Lawrence, VP of practice activities at the **American College of Obstetricians and Gynecologists**, told *BioCentury This Week*.

Responding to Friday’s announcement from KV, Lawrence told BioCentury the “price needs to be far closer to the compounded price than it is.”

George Saade, president of the **Society of Maternal-Fetal Medicine**, said in a statement that the “price remains too high and the reduction does not go far enough to improve cost-effective availability.”

Saade concluded: “Given the significant financial constraints on the health care system, and the lack of evidence for additional benefit from using Makena, SMFM feels that the compounded drug remains a better option.”

Sen. Brown and other members of Congress said the revised Makena pricing is still too high, and they urged FDA to continue to allow compounding pharmacies to compete against Makena.

On Friday, Rep. Allyson Schwartz (D-Pa.) said she is “deeply concerned that the initiatives set forth by the manufacturer still lack straight-forward affordability and transparency in pricing.”

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Matt Salo, National Association of State Medicaid Directors

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Makena by the numbers

Even with the price reduction it announced last Friday, **KV Pharmaceutical Co.** is asking the U.S. healthcare system, including cash-strapped Medicaid programs, to pay a substantial premium for an FDA-approved version of hydroxyprogesterone caproate compared with products available from compounding pharmacies.

Physicians typically prescribe 15-20 weekly injections of hydroxyprogesterone to women at high risk of premature delivery.

On Friday, KV reduced the list price of Makena to \$690 per dose from \$1,500 and capped the cost of a full course of therapy to a maximum of 15 injections for contracted health insurance plans and state Medicaid agencies.

The 23.1% rebate drug companies pay to Medicaid brings Medicaid's maximum cost for a course of treatment to \$7,959.

Wedgewood Pharmacy, one of the largest compounding pharmacies in the U.S., ships hydroxyprogesterone caproate nationwide for \$12.60 per dose or \$252 for a full course, which is 3% of the revised cost for

a full course of Makena.

Medicaid does not receive rebates on compounded hydroxyprogesterone.

KV received Orphan Drug status for Makena based on an estimate that 140,000 women per year meet the labeled indication: "women with a singleton pregnancy who have a history of singleton spontaneous preterm birth."

The company estimates government Medicaid programs pay the medical costs of 40-45% of pregnancies in the U.S.

If every eligible woman received Makena under the new pricing structure, Medicaid would pay \$446-\$501 million per year for the drug.

Medicaid's annual cost for compounded hydroxyprogesterone, assuming every woman received the maximum 20 doses at Wedgewood's price, would be \$14-\$16 million.

— *Steve Usdin*

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Room to maneuver

But KV may not have much more room to maneuver on Makena's price.

KV's March 31 10-Q notes numerous pending legal actions that could financially imperil the company, including "at least 43 pending product liability or other lawsuits that relate to the voluntary product recalls initiated by the company in late 2008 and early 2009." Of these, 29 plaintiffs allege that oversized tablets sold by KV caused deaths.

KV must pay over \$20 million in criminal fines associated with its distribution of adulterated drugs. The company also reports that it is the subject of several pending Justice Department and SEC investigations that could result in additional penalties.

The company hasn't finished paying for Makena, which it acquired from **Hologic Inc.** To date KV has paid \$82.5 million to Hologic for Makena, and has committed to pay an additional \$107.5 million.

Prior to the blow up, KV had projected it would have \$10-\$15 million in cash at March 31; on March 16, it raised \$225 million in secured notes bearing 12% interest and maturing on March 15, 2015.

Beyond its payments to Hologic, KV "has substantial debt and liabilities that comes due over the next several years and the pricing that the company must achieve from the sale of Makena, together with our sales of other products, must be substantial enough to allow us to meet these obligations, refinance or retire such debt and liabilities when due, and generate sufficient profits to ensure the Company's viability as a pharmaceutical company prior to the end of the Orphan Drug exclusivity period for Makena," according to the 10-Q.

"Our future business success in the next several years, as well as the continued operation of our company, depends critically upon our successful market launch of Makena and our ability to achieve revenues from the sale of Makena consistent with our business expectations," KV reported in the SEC filing.

"A failure to achieve these objectives and sufficient market success in selling Makena will materially adversely affect the success and viability of our company and would likely result in a default under our debt obligations."

Failure to "timely and successfully commercially launch Makena," and to achieve its revenue expectations for the product, "would result in material adverse impact on our results of operations and liquidity, and ability to continue as a going concern," KV added.

If KV fails to meet any of its payment obligations to Hologic when they come due, its rights to Makena would transfer back to Hologic (see "KV's Roller Coaster," A26).

KV declined to appear on *BioCentury This Week* and responded to questions for this report by providing copies of its prepared statements.

COMPANIES AND INSTITUTIONS MENTIONED

American College of Obstetricians and Gynecologists, Washington, D.C.

Centers for Medicaid and Medicare Services (CMS), Baltimore, Md.

Hologic Inc. (NASDAQ:HOLX), Bedford, Mass.

KV Pharmaceutical Co. (NYSE:KVA), Bridgeton, Mo.

March of Dimes, White Plains, N.Y.

National Association of State Medicaid Directors, Washington, D.C.

Society of Maternal-Fetal Medicine, Washington, D.C.

U.S. Food and Drug Administration (FDA), Silver Spring, Md.

Wedgewood Pharmacy, Swedesboro, N.J.