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K-V Bankruptcy May Hurt FDA's Unapproved Drug Initiative

By **Rachel Slajda**

Law360, New York (August 08, 2012, 5:40 PM ET) -- K-V Pharmaceutical Co. claims a U.S. Food and Drug Administration decision to allow cheap compounded drugs to compete with its newly approved brand-name drug drove it to bankruptcy, a move experts say may undermine a key FDA initiative to get unapproved drugs reviewed and regulated.

In its Chapter 11 bankruptcy filing Saturday, K-V blamed its financial troubles on the FDA for undermining its exclusivity on Makena, a drug meant to prevent preterm births. Makena was approved in February 2011, as part of the FDA's efforts to bring unapproved drugs — including some sold out of compound pharmacies — through the review process, getting them standardized and tested for safety and efficacy.

But K-V claims the FDA never let its drug, which was supposed to bring in up to $2 billion, get off the ground. The agency said in March 2011 it wouldn't go after compounding pharmacies — which had been making the active ingredient, known as 17-HPC, for years — for continuing to sell what amounted to an unapproved version of the drug.

Compound pharmacies put together custom medications at a doctor's request. For example, they can create customized doses that are higher or lower than the FDA-approved dose, or put an active ingredient in liquid form for a patient who can't swallow a pill.

The compounders' drug was so much cheaper than Makena, at $10 to $20 an injection versus $1,500 an injection, that Makena didn't stand much of a chance. The FDA's enforcement decision gave Medicaid programs cover to insist on the compounded version rather than paying for Makena. K-V later dropped the price to $690, under pressure from Congress.

"Here you essentially allowed an approved product to die," Steve Mahinka, chairman of Morgan Lewis & Bockius LLP's life sciences and health care interdisciplinary group, told Law360.

K-V wasn't wrong to assume that it had a monopoly, experts say. Makena was approved as an orphan drug, granting it seven years of exclusivity, as part of the FDA's efforts to encourage drugmakers to sponsor an already available but unapproved drug. K-V was acting on that basis when it priced the drug so high, experts say.

But K-V's rude awakening, if interpreted as a warning by other drugmakers, could damage the FDA's ongoing efforts to get companies to sponsor an unapproved drug through the review process so it can be regulated.

"This company now has declared bankruptcy. Is that the kind of incentive you want to give, if you are the FDA, for the future?" Mahinka said. "You can say it won't come up very often ... but what company is now going to look at an underserved market, which pharmacy compounding has been serving, spend a whole lot of money on approval, and not be able to sell it?"

Frederick Ball, a partner at Duane Morris LLP who represents compounding pharmacies, said that although the FDA was within its rights, K-V makes a good point against the agency.

"Their argument is they went through safety and efficacy testing," Ball said. "They have a good policy argument: If you want companies to do safety and efficacy testing, you have to make sure their exclusivity is not going to be undermined by compounding pharmacies."

K-V claims the agency broke the law by not stopping the compounders and effectively denying the company its exclusivity period. In a suit filed in D.C. District Court in July, K-V accused the FDA of putting financial considerations over medical ones.

But experts say the FDA acted well within its authority to decide whether or not to take enforcement action against the compounders even if — as is likely — the drug's cost and Medicaid's reluctance to cover it played a role.

"It is an illustration of the use of enforcement discretion to accommodate payment concerns. Pure and simple. Is the FDA within its power to allow the pharmacy compounders to continue? Yes," Mahinka said.

"Unless these compounding pharmacies are selling something that's dangerous or against the law, you can't force the agency to act. ... Federal agencies exercise enforcement discretion all the time," Ball said.

He added that it's a safe assumption that price was a factor in the FDA's decision, although federal agencies don't have to explain their rationale for enforcement decisions.

"The FDA could read the tea leaves from congressional hearings over the pricing. You have to remember where the FDA gets its funding," Ball said.

In a hearing Tuesday over K-V's request for an injunction forcing the FDA to stop the pharmacies, U.S. District Judge Amy Berman Jackson appeared to agree that the FDA was acting within its discretion.

"I'm worried about the notion that I'm now overseeing this thoroughly discretionary act," she told K-V's lawyers. "You want me to be the super-law-enforcement officer over the FDA."

--Additional reporting by Erica Teichert and Lisa Uhlman. Editing by John Quinn and Katherine Rautenberg.