Generic Drug Manufacturer ETHEX Corp. Is Being Shut Down By KV Pharmceuticals

Troubled Company Pleads Guilty To Criminal Charges, Pay $27.6 Million In Fines And Restitution For Its Conduct Related To Quality-Control Issues

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 25, 2010; see http://bit.ly/9TrXHn)

We last wrote about the troubled generic drug manufacturer ETHEX Corp. a little more than a year ago, when we posted this article: "January 2009: ETHEX Corp. Issues Voluntary Recall Of All Pills Due To Suspected Manufacturing Problems".

Now, in February 2010, we know how the story ends for ETHEX -- for the most part, at least.

From a February 25, 2010 article, "KV Pharmaceutical to plead guilty, pay $27.6M, close generics business", published by the *St. Louis Business Journal*:

KV Pharmaceutical Co. must pay $27.6 million in fines and restitution, and plans to cease its generic drugs business after pleading guilty to criminal charges for not disclosing problems with two of its drugs.....

Bridgeton, Mo.-based KV said Thursday its subsidiary, Ethex Corp., plans to plead guilty to two felony counts of failure in 2008 to file field alerts for the generic drugs Dextroamphetamine, a stimulant used to treat ADHD, and Propafenone, which treats rapid heart beats. The company then plans to cease operations of Ethex. The U.S. Food and Drug Administration requires that companies file field alerts to quickly identify drugs that pose potential safety threats from problems such as contamination or mislabeling.

KV's interim Chief Executive David Van Vliet declined to disclose the specifics of what the problems with the drugs exactly were.

Van Vliet said the company will now focus on regaining FDA compliance so it can return to making both branded and generic drugs under Ethex's parent company, KV, which retains all related intellectual property, including drug applications and the ability to conduct marketing and distribution of all of its previously approved products. [Emphasis added]

It remains to be seen whether the U.S. Attorney for the Eastern District of Missouri, the U.S. Department of Justice (DOJ), or the U.S. Food and Drug Administration (FDA) will release details about the extent of the quality control problems at ETHEX and whether those problems resulted in any known-cases of harm to patients using any of the sub-standard generic drugs made by ETHEX.

If you are aware of a drug injury case involving an ETHEX product, we would be interested in hearing about it. You can do so by posting a Comment below or sending me a private email.

For more articles about quality-control issues at various generic drug companies, view our collection of stories at the Generic Drug Safety part of our blog Archives.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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