

Department of Justice
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Eastern District of Pennsylvania

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Bucks County Drug Manufacturer and Two Executives Charged With Conspiracy to Defraud the FDA

KVK-TECH, Inc., Murty Vepuri and Ashvin Panchal Allegedly Distributed Unapproved Drugs and Lied to Drug Regulators

PHILADELPHIA – Acting United States Attorney Jennifer Arbittier Williams announced that generic drug manufacturer KVK-TECH, Inc., headquartered in Newtown, PA, Murty Vepuri (69), and Ashvin Panchal, (50), also of Newtown, were charged by Indictment with conspiracy to defraud the United States Food & Drug Administration (“FDA”) arising from the alleged distribution of unapproved drugs as well as alleged efforts to mislead the FDA and conceal information which could impact drug safety and effectiveness. KVK-TECH was also charged with one count of mail fraud arising from the alleged sale of unapproved drugs to customers who believed the drugs were made with the approval of the FDA.

According to the Indictment, from approximately October 2010 through at least March 2015, Vepuri, the *de facto* owner of KVK-TECH, and Panchal, the company’s head of Quality Assurance, conspired to defraud the United States and its agencies by impeding, impairing, and defeating FDA’s mission to protect the health and safety of the public by ensuring that drugs marketed and distributed in the United States are safe and effective for their intended uses.

As alleged in the Indictment, Vepuri directed KVK-TECH’s day-to-day operations and made all key business decisions for the company, including decisions related to drug regulatory requirements, drug composition, drug manufacturing quality, purity, and potency. However, Vepuri – who previously owned a generic drug manufacturer in New Jersey that was subject to a restraining order due to ongoing FDA violations – is charged with hiding his involvement in KVK-TECH by placing its ownership in private trusts for the benefit of his children. Vepuri then allegedly represented to the FDA that he was merely an advisor or consultant to KVK-TECH, when in reality he exercised unchecked authority over the company.

As alleged, under Vepuri’s control, KVK-TECH ignored regulatory requirements that had the potential to slow the manufacture, distribution, and sales of its drugs. Vepuri and Panchal are also charged with having provided false explanations to the FDA when inspectors identified violations. Often, Vepuri and Panchal attributed regulatory failures to a mistake or misunderstanding, and KVK-TECH would falsely assure the FDA that violations had been addressed when they knew no corrective and preventative actions had been taken.

The Indictment highlights KVK-TECH’s conduct with regard to Hydroxyzine, a KVK-TECH prescription drug for the treatment of anxiety, for which Vepuri purchased an active pharmaceutical ingredient (“API”) made in Mexico by Dr. Reddy’s Laboratories (“DRL Mexico”). DRL Mexico was not an FDA-approved source. To the contrary, as alleged, the defendants knew that DRL Mexico’s API was considered adulterated by the FDA due to significant violations of good manufacturing practices (cGMP) at DRL Mexico’s manufacturing plant. The cGMP violations were so severe that the FDA issued an import alert for all DRL Mexico API from July 2011 through July 2012. Nonetheless, from 2011 through 2013, KVK-TECH is charged with having knowingly distributed more than 383,000 bottles of the unapproved Hydroxyzine without the FDA’s knowledge or approval.

“FDA laws and regulations regarding drug composition, manufacturing, quality, and related controls are designed to protect Americans’ health and safety – so we can all be confident that our prescription medications will be safe and effective,” said Acting U.S. Attorney Williams. “When companies attempt to game the system to avoid these regulations and increase their profits, the ramifications are potentially catastrophic. As this Indictment makes clear, any individuals or companies that try to evade the law in this manner will be brought to justice.”

“An important mission of the Office of Inspector General is to investigate allegations of fraud against the Department of Labor’s programs. We will continue to work with our law enforcement partners to investigate these types of allegations,” stated Syreeta Scott, Acting Special Agent-in-Charge, Philadelphia Region, U.S. Department of Labor Office of Inspector General.

If convicted, Vepuri and Panchal each face a maximum possible sentence of five years in prison, three years of supervised release, a \$250,000 fine and other financial penalties including forfeiture. KVK-TECH faces fines up to \$4 million and other financial penalties such as forfeiture and probation. The parties also face mandatory exclusion from participating in federal programs.

The case was investigated by the FDA-Office of Criminal Investigations, Homeland Security Investigations, and the Department of Labor Office of Inspector General, and is being prosecuted by Assistant United States Attorneys M. Beth Leahy and Patrick J. Murray, and Ross Goldstein, Senior Litigation Counsel for the Department of Justice Consumer Protection Branch.

An indictment, information, or criminal complaint is an accusation. A defendant is presumed innocent unless and until proven guilty.

Topic(s):
Prescription Drugs

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