

NEWS

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Sixth Former Manager at Generic Drug Manufacturer Able Labs Pleads Guilty, Admits Drug Adulteration Conspiracy

(More)

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NEWARK – A former Manager and Associate Director in the Research and Development Department at Able Laboratories, a now-defunct New Jersey generic drug manufacturer, pleaded guilty today to a conspiracy involving the adulteration of a generic drug, U.S. Attorney Christopher J. Christie announced.

Vithal Patel, 52, of Monroe Township, pleaded guilty before U.S. District Judge Susan D. Wigenton to a one-count criminal Information charging him with conspiracy to distribute misbranded and adulterated drugs. He faces a statutory maximum penalty of five years in federal prison and a \$250,000 fine. Judge Wigenton scheduled sentencing for Dec. 18; Patel is free on a \$250,000 personal recognizance bond.

From the late 1990's through mid-2005, Able grew from a fledgling generic drug manufacturer to a company which employed approximately 500 people at its South Plainfield laboratory and its Cranbury headquarters. Able, formerly a publicly traded company, manufactured dozens of wide-ranging generic pharmaceutical products for treatments related to serious cardiac and psychiatric conditions, as well as afflictions effecting children.

Patel is the sixth Able manager to plead guilty in the case.

The government charged a broad-based fraud scheme involving numerous drug products, and conduct which included manipulating the approved manufacturing process for drug products and improperly changing test parameters to obtain satisfactory test results. Each of the defendants who pleaded guilty previously outlined their supervisory roles and participation with other chemists which resulted in flouting, altering and manipulating testing and reporting requirements which were required to be submitted to the FDA.

Patel admitted that, after being promoted to Manager in the Research and Development Department in early 2003, he became involved in a criminal conspiracy directed by a high-level executive, identified in court today as “K.H.” Patel admitted that he conspired with K.H. and others to alter the approved manufacturing process for Promethazine, which Able was distributing to the general public.

In addition, Patel acknowledged direct conversations with Able’s CEO regarding problematic test results for Lithium Carbonate extended release tablets. Two other Able managers, Jyotin Parikh and Shashikant Shah, each described at their respective guilty pleas a secret project, directed by the highest levels of the Company, which included forging data in chemist and laboratory notebooks and binders to obtain the FDA’s approval to manufacture Lithium Carbonate extended release tablets, which was a new generic drug product for Able.

In March and April, five other managers at Able pleaded guilty to a conspiracy that

flouted mandated quality control tests, and failure to record unsatisfactory test results, which are required to ensure that the distributed medications were safe and effective, according to Assistant U.S. Attorney Robert Kirsch, who is prosecuting the cases. The other five managers were:

- Shashikant Shah, of Dayton, N.J., who served as Able's V.P. of Quality Assurance/Quality Control and Regulatory Affairs;
- Ashish Macwan, of Tinton Falls, N.J., who served as Able's Group Leader, Supervisor, and Assistant Manager in its Quality Control Department;
- Jyotin Parikh, of Clifton, N.J., who served as Able's Laboratory Manager in its Quality Control Department;
- Jose Concepcion, of Hazlet, N.J., who served as Able's Group Leader and Supervisor in Able's Quality Control Department; and
- Dilip Patel, of Iselin, N.J. (no relation to Vithal Patel), who served as Supervisor of Analytical Control in Able's Quality Control Department.

Able was a public company which traded on the NASDAQ exchange. In mid-May 2005, at its height, Able traded at more than \$26 per-share. At the close of trading on May 19, 2005, the day after the Company announced it was suspending shipments of its entire product line, as well as recalling certain products because of indications of improper laboratory practices, its value plummeted 75 percent, to approximately \$6.36 per share. Overnight, the Company had a market capitalization loss of approximately \$340 million, Kirsch said. Able subsequently filed for bankruptcy under Chapter 11 and is no longer operational.

In determining the actual sentence for Mr. Patel, Judge Wigenton will consult the U.S. Sentencing Guidelines, which provide appropriate sentencing ranges that take into account the severity and characteristics of the offense, the defendant's criminal history, if any, and other factors. The judge, however, is not bound by the guidelines in determining a sentence.

Parole has been abolished in the federal system. Defendants who are given custodial terms must serve nearly all that time.

Christie credited the Special Agents from the Food and Drug Administration, Office of Criminal Investigations/Metro Washington Field Office, under the direction of Special Agent in Charge Kim A. Rice; Postal Inspectors from the U.S. Postal Inspection Service, under the direction of Acting Postal Inspector in Charge Eddie C. Woodson, and Special

Agents of the FBI, under the direction of Special Agent in Charge Weysan Dun.

The government is represented by Assistant U.S. Attorney Robert Kirsch, of the Securities and Health Care Fraud Unit of the U.S. Attorney's Office in New Newark.

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Defense Counsel:

Christopher Porrino, Roseland, N.J.