

NEWS

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Fifth Manager Pleads Guilty in Able Labs Generic Drug Fraud Conspiracy

(More)

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NEWARK – A former quality control manager at Able Laboratories, a now-defunct New Jersey generic drug manufacturer, pleaded guilty today to a conspiracy involving rampant manipulation and falsification of testing data of its drugs, U.S. Attorney Christopher J. Christie announced.

Dilip Patel, 44, of Iselin, 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 maximum term of five years in federal prison and a \$250,000 fine.

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.

In March, four other managers at Able pleaded guilty to a conspiracy that flouted required quality control tests designed to ensure that the distributed prescription medications were safe and effective, according to Robert Kirsch, the Assistant U.S. Attorney who is handling each of the prosecutions. The other four 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; and
- Jose Concepcion, of Hazlet, N.J., who served as Able's Group Leader and Supervisor in Able's Quality Control Department.

Patel had not been previously charged, and his guilty plea was his first appearance in Court. Judge Wigenton set bail at \$100,000 secured by equity in his home in Iselin. Sentencing was scheduled for Aug. 16 The sentencings for the other defendants have been set for July 24.

The government charged a broad-based fraud scheme involving a series of drug products, and conduct which ranged from improperly changing test parameters to obtain satisfactory test results to a secret project which included forging data in chemist

laboratory notebooks and binders in order to obtain the FDA's approval to manufacture a new generic drug product. Each of the five defendants, including Patel, 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.

Under federal law, Able was required to submit its drug products through a testing protocol designed to ensure that its manufactured products were "safe and effective," according to the government's charging document. Able was required to complete and maintain accurate testing data, as well as submit the information to the Food and Drug Administration (FDA), the federal agency which reviews and regulates drug manufacturers.

Patel was initially hired as a chemist in Able's Quality Control Department, and was first promoted to supervisor of analytical control, and promoted again to Quality Control Manager. Patel admitted to participating in a criminal conspiracy from approximately 1999 through mid-2005, and stated that he was directed by the highest levels of management, including the CEO and an individual identified as "K.H." to falsify and manipulate failing test results, after which, the drugs were then sold and distributed to consumers in the marketplace. Patel admitted that when he expressed reservations and concerns about the illegal conduct, K.H. advised him he would be fired should he refuse to do as instructed.

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, 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 Postal Inspector in Charge Thomas C. Van de Merlen; and Special Agents of the FBI, under the direction of Acting Special Agent in Charge Pedro Ruiz, for their persistence and skill in this investigation.

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 Newark.

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Defense Counsel:
Chris Fleming, East Brunswick, N.J.