

NEWS

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FOR IMMEDIATE RELEASE
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Four Managers of Now-Defunct N.J. Generic Drug Maker
Admit Fraud that Led to Collapse and Bankruptcy of Company

(More)

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NEWARK – A former Vice President in charge of the Quality Control Department and three supervisory chemists at now-defunct New Jersey generic drug manufacturer Able Laboratories pleaded guilty today to a conspiracy involving the rampant falsification and manipulation of testing data of its drugs, U.S. Attorney Christopher J. Christie announced.

At the time of its collapse in mid-2005, Able Laboratories, Inc. employed approximately 500 people at its South Plainfield laboratory and its Cranbury headquarters. Able manufactured wide-ranging generic pharmaceutical products for treatments related to serious cardiac and psychiatric conditions, as well as afflictions effecting children. Charging documents filed by the U.S. Attorney’s Office outline the Company’s flouting the required quality control tests on its drug products, which were designed to ensure that the distributed prescription medications were safe and effective.

Pleading guilty to criminal Informations were:

- Shashikant Shah, 65, of Dayton, N.J. – served as Able’s V.P. of Quality Assurance/Quality Control and Regulatory Affairs from mid-2001 through the end of 2004 – to one count of conspiracy to commit securities fraud and to distribute misbranded and adulterated drugs.
- Jyotin Parikh, 56, of Clifton, N.J. – served as Able’s Laboratory Manager in its Quality Control Department from mid-2000 through the beginning of 2005 – to one count of conspiracy to distribute misbranded and adulterated drugs.
- Ashish Macwan, 47, of Tinton Falls, N.J. – served as Able’s Group Leader, Supervisor, and Assistant Manager in its Quality Control Department – to one count of conspiracy to distribute misbranded and adulterated drugs.
- Jose Concepcion, 57, of Hazlet, N.J. – served as Able’s Group Leader and Supervisor in Able’s Quality Control Department – to one count of conspiracy to distribute misbranded and adulterated drugs.

All four face a statutory maximum penalty of five years in federal prison and a \$250,000 fine. All four had not been previously charged, and thus their guilty pleas were their first appearances in court. Judge Wigenton set bail for Shah at \$500,000 secured by equity in his home; the other defendants’ bail was set at \$100,000 unsecured. Judge Wigenton scheduled sentencings for July 24.

“The damage from the fraud at Able Labs was devastatingly complete,” said Christie. “Consumers were put at risk, a company that employed 500 people was destroyed, and shareholders were left with nothing in the end. This is the legacy of the fraud perpetrated

at Able Labs by these defendants.”

“Those who willfully falsify and manipulate the various tests required during the manufacturing process put the public health at risk, and do so at their own peril,” said Kim A. Rice, Special Agent in Charge of the Food and Drug Administration in Washington, which investigated the case.

The investigation is continuing.

Collapse of the Generic Drug-Maker

The Information against Shah charges that the criminal conspiracy spanned 1999 through May 19, 2005, a period when the Company and its leaders publicly touted Able’s enormous growth and expansion. From the end of 1999 through mid-2002, Able’s shares traded at prices ranging from only 17 cents per share to 55 cents per share. Thereafter, as Able’s sales and its product lines increased, the Company’s stock price dramatically increased, culminating in its all-time high of approximately \$26.50 per share, which was recorded in mid-May 2005.

On May 19, 2005, 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. At the close of trading on May 19, 2005, Able’s stock plummeted 75 percent, from over \$24 per share at the close on May 18 to approximately \$6.36 per share at the close on May 19, resulting in a market loss of approximately \$340 million, said Robert Kirsch, the Assistant U.S. Attorney who handled the prosecutions.

The Company subsequently filed for bankruptcy under Chapter 11, and at the end of July 2005, was delisted as a publicly-traded security on the NASDAQ exchange.

Falsification of Testing Data

During their guilty plea hearings held before U.S. District Judge Susan D. Wigenton, in Newark, all four admitted participating in a conspiracy spanning from approximately 1999 through mid-2005. The four 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. The FDA is charged with reviewing and monitoring generic drug manufactures to ensure that the drug products are safe, and that they contain the required drug identity, strength, quality and purity levels.

The defendants admitted to 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.

Shah's Insider Trades

Shah, as part of his one-Count Criminal Information, also admitted to conspiring to commit securities fraud, specifically insider trading, relating to a series of his stock sales from August 2003 through the end of 2004, while he was aware of the pervasive illegal laboratory practices.

Shah admitted that he, and other high-level Able executives, received stock options from the Company, which were exercised according to the terms and conditions of Stock Trading Plans. Shah admitted that at the time that he and the other high-level executives entered into these Stock Trading Plans, they were well-aware of the ongoing serious laboratory improprieties. The insider trades netted Shah in excess of \$900,000 in profit, Kirsch said.

Also today, the Securities and Exchange Commission filed a civil action in federal court in Newark alleging insider trading against Shah relating to the same stock trades at issue in the criminal case. Shah consented to a final judgment wherein he is permanently prohibited from violating the anti-fraud provisions of the federal securities laws, and prohibited for five years from serving as an officer or director of a publicly traded company. Shah has also agreed to disgorge his ill-gotten gains, along with prejudgment interest, as well as a civil penalty, to be determined by the Court at a later date.

In determining the actual sentence, Judge Wigenton will consult the advisory 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 the investigation.

Christie also credited the SEC, under the direction of Linda Chatman Thomsen, Director

of the Division of Enforcement, in Washington, D.C., for their valuable assistance in developing the case.

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:

Shah: Andrew Krulwich, Esq., and Roderick Thomas, Esq., Washington, D.C.

Parikh: Alain Leibman, Esq., of Roseland, N.J.

Macwan: Henry Klingeman, of Newark, N.J.

Concepcion: Stacy Biancamano, Esq., Assistant Federal Public Defender, Newark, N.J.