2006R01206/RAK

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.
v.	:	Criminal No.
SHASHIKANT SHAH	:	18 U.S.C. § 371

INFORMATION

The defendant having waived in open court prosecution by Indictment, the United States Attorney for the District of New Jersey charges:

Able Laboratories, Inc.

1. At all times relevant to this Information, Able Laboratories, Inc. ["Able" or the "Company"], a corporation incorporated in Delaware with its principal place of business in New Jersey, was a manufacturer and distributor of generic drug products. Specifically, Able developed, manufactured, and sold several generic drug products, including, but not limited to, pharmaceutical drug products ranging from treatments for serious cardiac and psychiatric conditions to prescription pain relievers. Able's laboratory facilities were located in South Plainfield, New Jersey and its corporate headquarters were located in Cranbury, New Jersey.

2. Able had, at times, approximately 500 employees and, as of on or about November 19, 2002, was a publicly-held corporation which traded on the Nasdaq National Market System ["NASDAQ"] under the symbol "ABRX." Prior to that, Able was listed for

trade on the Over-the-Counter Bulletin Board.

Defendant

3. Defendant Shashikant Shah [“**SHAH**”] was a resident of Dayton, New Jersey. From in or around mid-1999 through on or about December 27, 2004, he served as Able’s Vice President of Quality Assurance/Quality Control and Regulatory Affairs. Defendant **SHAH’s** annual salary increased from approximately $100,000 in or about 1999 to $200,000 in or about 2004.

4. Defendant **SHAH** reported directly to an individual who was the Company’s Chief Executive Officer and Chairman of the Board of Directors. After his tenure as an officer and employee of the Company ended, defendant **SHAH** became a Quality Control Consultant pursuant to a consulting agreement with the Company. On or about May 27, 2005, his consulting agreement was terminated by the Company.

5. As Vice President of Quality Assurance/Quality Control and Regulatory Affairs, defendant **SHAH** was responsible for supervising as many as 100 employees, including numerous managers and supervisors, and several dozen laboratory chemists.

6. Among other responsibilities, defendant **SHAH**:

a. supervised the quality control and testing processes of the generic drug products manufactured and sold by the Company;

b. ensured compliance with current Good Manufacturing

Practices [“GMPs”], as required by the Food and Drug Administration [“FDA”], and Standard Operating Procedures [“SOPs”], as established by the Company;

c. oversaw product quality, product efficacy, customer complaints, adverse drug reporting, product investigations, annual product reviews; and

d. authorized the submission of data to the FDA for the purpose of ensuring Able’s pharmaceutical product quality and efficacy.

Able’s Anti-Insider Trading Policy

7. As late as December 2002, Able issued a memorandum to its Officers, Directors, employees, and others entitled “Insider Trading and Non-Disclosure Policies and Procedures” [“Anti-Insider Trading Memorandum” or “memorandum”]. Page 1 of the memorandum, portions of which were emphasized in bold and underlined typeset as set forth below, provided in pertinent part:

> **If you know material inside information about the Company, you must not buy or sell the Company’s stock until the information has been fully disclosed to the public through proper channels.** Trading is prohibited even if the information is well known within the Company ... Failure to comply with these rules will give rise to civil and criminal liability on your part under the securities laws.

8. The first entry in the Anti-Insider Trading Memorandum provides a non-exhaustive list setting forth the “kinds of

information that are particularly likely" to be material, including: "the receipt or delay of any ANDA[1] approvals for new products, significant changes in any important service or product development effort, or any significant operating problems or regulatory issues ...."

Shah's Stock Trading Plans

9. Beginning in mid-2003, defendant **SHAH,** along with several other high level Company executives [the "other trading executives"], received stock options from the Company, which options were to be exercised according to two Stock Trading Plans. Execution of the Stock Trading Plans authorized a third-party broker to exercise a specific number of options at a prescribed price [the "strike price"], which resulted in the automatic purchase and sale of Company shares of stock on behalf of defendant **SHAH** and the other trading executives who were authorized to participate in the Plans, at certain defined times which were also described in the Plans.

10. Defendant **SHAH** and the other trading executives, entered into individualized Stock Trading Plans [the "First Trading Plans"] which went into effect in or around August 2003. Defendant **SHAH**'s First Trading Plan authorized the third-party broker to exercise on **SHAH**'s behalf a maximum of 6,000 options,

[1]"ANDA" stands for Abbreviated New Drug Application and is described in greater detail in paragraph 18.

at a strike price of $3.75 per share, during six separate time-periods which were set forth in the First Trading Plan, and which concluded in or around June 2004. The First Trading Plan was amended in or around December 2003 to increase the maximum number of options that could be exercised during the remaining subsequent prescribed trading periods to 10,000.

11. The First Trading Plan, which was signed by defendant **SHAH**, under the heading of "Representations, Warranties and Covenants," included the following attestation: "As of [August 4, 2003], Seller [**SHAH**] is not aware of any material nonpublic information concerning the Issuer [Able] or its securities. Seller [**SHAH**] is entering into this Sales Plan in good faith and not as part of a plan or scheme to evade compliance with the federal securities laws." At or about the same time, the other trading executives entered into first Stock Trading Plans which required the identical attestation.

12. Defendant **SHAH** and the other trading executives entered into a second set of individualized Stock Trading Plans [the "Second Trading Plans"] which went into effect in or around August 2004. Defendant **SHAH**'s Second Trading Plan authorized the third-party broker to exercise on **SHAH**'s behalf a maximum of 5,000 options, at a strike price of $3.75 per share, during two separate time-periods which were set forth in the Second Trading Plan, and which concluded in or around December 2004.

13. The Second Trading Plan, which was signed by defendant **SHAH**, under the heading of "Representations, Warranties and Covenants," included the following attestation: "As of [August 1, 2004], Seller [**SHAH**] is not aware of any material nonpublic information concerning the Issuer [Able] or its securities. Seller [**SHAH**] is entering into this Sales Plan in good faith and not as part of a plan or scheme to evade compliance with the federal securities laws." At or about the same time, the other trading executives entered into second Stock Trading Plans which required the identical attestation.

Shah's Certifications to the Securities and Exchange Commission

14. On several occasions from on or about August 4, 2004 through on or about December 1, 2004, defendant **SHAH** and the other trading executives signed, or authorized another to sign on their behalf, SEC Form 144s which were submitted to the Securities and Exchange Commission ["SEC"], and which documented the shares of Able stock defendant **SHAH** and the other trading executives sold under their First and Second Trading Plans.

15. In the Form 144s, defendant **SHAH** and the other trading executives, under penalty of criminal prosecution, each represented that "by signing this notice ... he does not know any material adverse information in regard to the current and prospective operations of the Issuer [Able] of the securities to be sold which has not been publicly disclosed."

16. In addition to the execution of the SEC Form 144s, defendant **SHAH** and the other trading executives also signed corresponding "SEC Rule 144 Seller's Representation Letters," which were submitted to the sales broker who executed the sale of Able shares of stock under the First and Second Trading Plans on behalf of defendant **SHAH** and the other trading executives. In these letters, defendant **SHAH** and the other trading executives each represented that they knew "of no important development affecting the Company or its business or products which has not been made public ...."

United States Food and Drug Administration ["FDA"]

17. The FDA was an agency of the United States charged with protecting the health and safety of the American public by ensuring, among other things, that drug products for human and veterinary use were safe and effective for their intended uses and that they bore labeling that was not false or misleading.

18. The FDA was authorized to enforce the Federal Food, Drug, and Cosmetic Act ["FD&C Act"], Title 21, United States Code, Sections 301, et seq., which governed the manufacturing and marketing of drugs in interstate commerce.

19. As part of its responsibilities, the FDA reviewed, approved and monitored the manufacture of generic drugs, which were chemical copies of innovator, or pioneer, drug products. Prior to marketing a generic drug product, the FD&C Act required

an applicant to submit an ANDA to the FDA, which included data and information confirming, among other things, that the manufacturer produced a product that was consistently equivalent to the innovator product and was safe and effective.

20. The FD&C Act prohibited the introduction or delivery for introduction into interstate commerce of misbranded or adulterated drugs. Under the FD&C Act, a drug was misbranded "if its labeling was false or misleading in any particular." 21 U.S.C. § 352(a).

21. Under the FD&C Act, a drug was adulterated if it was not manufactured in conformance with GMPs, which were designed to ensure that the drug was safe, and that it had the requisite identity, strength, quality, and purity characteristics. 21 U.S.C. § 351(a)(2)(B).

22. The FD&C Act required drug manufacturers to keep and maintain documentation including the batch production records for each batch of drug product manufactured. In particular, manufacturers were required to record complete information relating to the production of each batch including, but not limited to, identification of each component, the laboratory control test results, and documentation for each step in the drug's manufacture. 21 C.F.R. § 211.188. In addition, laboratory records were required to include complete data derived from all tests performed, and to indicate the identity of the

persons who performed and reviewed those tests. 21 C.F.R. § 211.194.

23. The FD&C Act also required drug manufacturers to make certain reports regarding failures or deviations in the manufacturing processes. 21 U.S.C. § 331(e). Manufacturers had a continuing duty to disclose any failure of a distributed batch of drugs to meet the specifications established for it in the ANDA. 21 C.F.R. §§ 314.81(b)(2)(iv) and 314.98(c).

24. The FDA carried out its responsibilities by, among other things:

a. inspecting facilities where drug products were manufactured;

b. examining the manufacturer's records at such facilities to determine whether the drug products were manufactured under conditions designed to ensure their quality;

c. examining the finished drug products; and

d. where appropriate, preventing improperly manufactured or improperly labeled drugs from reaching the marketplace or causing the seizure of such drugs if they had already been distributed.

GMPs and SOPs

25. Among other things, GMPs required drug manufacturers to keep accurate, complete, and contemporaneous records of manufacturing and testing processes, so that the manufacturer and

the FDA could monitor the manufacturing and testing processes, the conduct of employees throughout the manufacturing and testing processes, and the safety, effectiveness, and integrity of the finished products. 21 C.F.R. § 211.

26. In order to comply with the FDA's GMPs, Able's SOPs established protocols for investigating, logging and archiving any aberrant, deviant or failing analytical laboratory results, which were referred to as "Out of Specification" ["OOS"]. For example, Able's SOPs required chemists to timely notify a Supervisory Chemist of any deviation from the prescribed satisfactory testing results, and to assist the Supervisory Chemist in the preparation of a Laboratory Investigation Report ["LIR"].

The Securities and Exchange Commission ["SEC"]

27. The SEC was an independent agency of the United States government which was charged by law with preserving honest and efficient markets in securities. Among other things, the SEC was charged by law with the duty of protecting investors by regulating and monitoring the purchase and sale of publicly-traded securities. The NASDAQ was among the national securities markets regulated by the SEC.

28. The anti-fraud provisions of the federal securities laws, including Section 10(b) of the Securities Exchange Act of 1934, codified at Title 15, United States Code, Section 78j(b),

and Rule 10b-5 thereunder, codified at Title 17, Code of Federal Regulations, Section 240.10b-5, prohibited fraudulent activities in connection with the buying or selling of securities, including "insider trading."

29. Insider trading was generally defined as trading a security, in violation of a known duty of trust and confidence, on the basis of material, nonpublic information about a public company. Rule 10b5-1, codified at Title 17, Code of Federal Regulations, Section 240.10b5-1, effective October 23, 2000, provided that a purchase or sale of a security was made "on the basis of" material, non-public information when the person making the trade was aware of the material, non-public information at the time of the trade.

THE CONSPIRACY

30. From in or around the end of 1999 through on or about May 19, 2005, in the District of New Jersey, and elsewhere, defendant

SHASHIKANT SHAH

did knowingly and willfully conspire and agree with others to commit offenses against the United States, that is:

a. by the use of means of instrumentalities of interstate commerce, the mails, and the facilities of national securities exchanges, directly and indirectly, to use and employ manipulative and deceptive devices and contrivances in

contravention of Title 17, Code of Federal Regulations, Section 240.10b-5 (“Rule 10b-5") in connection with the purchase and sale of Able securities, by (i) employing devices, schemes, and artifices to defraud; (ii) making or causing to be made untrue statements of material facts and omitting to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; and (iii) engaging in acts, practices, and courses of business which operated and would operate as a fraud and deceit on holders of Able securities and other members of the investing public, contrary to Title 15, United States Code, Sections 78j(b) and 78ff(a) and Rule 10b-5; and

b. with an intent to defraud and mislead, to introduce and deliver for introduction into interstate commerce a drug that was adulterated and misbranded, contrary to Title 21, United States Code, Sections 331(a) and 333(a)(2).

The Objects of the Conspiracy

31. The principal objects of the conspiracy were for defendant **SHAH** and his co-conspirators to (a) enrich themselves by selling shares of Company stock pursuant to Stock Trading Plans while in possession of material non-public information, namely that Able was distributing generic drug products which had failed the requisite testing; and (b) distribute adulterated and misbranded generic drug products.

Means and Methods of the Conspiracy

32. Throughout the conspiracy, defendant **SHAH** and his co-conspirators employed various means and methods to carry out the conspiracy and to achieve its unlawful objects. Among the means and methods employed by the defendant and his co-conspirators were those set forth in paragraphs 33 through 43 below.

33. Defendant **SHAH** and his co-conspirators impaired, impeded, defeated and obstructed the FDA's lawful government function to approve the manufacture and distribution of generic drug products by:

a. violating GMPs and SOPs by failing to properly investigate, log and archive questionable, aberrant, and unacceptable laboratory results so that the Company could conceal improprieties and continue to distribute and sell its drug products;

b. manipulating and falsifying testing data and information to conceal from the FDA failing laboratory results relating to Able's generic drug products; and

c. creating and maintaining false, fraudulent, and inaccurate test results to make it appear that drug products had the requisite identity, strength, quality, and purity characteristics so the drug products could be distributed and sold to increase the Company's sales and profit.

34. Defendant **SHAH** and his co-conspirators created and

maintained false, fraudulent, and inaccurate data and records to obtain the FDA's approval for ANDAs and the FDA's authorization to manufacture new product lines in order to increase the Company's sales and profit.

Able's Purported Expansion and Corresponding Trading History

35. Defendant **SHAH** and his co-conspirators distributed and caused to be distributed adulterated and misbranded generic drug products while Able publicly touted the growth and expansion of the Company in press releases and publicly filed documents with the SEC.

36. In the early phase of the conspiracy, from in or around the end of 1999 through in or around mid-2002, Able's shares traded at prices ranging from $.17 (17 cents) per share to $.55 (55 cents) per share. As Able's generic drug sales and product lines expanded, the Company's stock price continued to generally and dramatically increase. For example:

a. On or about May 6, 2002, Able filed its Form 10-Q with the SEC for the financial quarter which ended on March 31, 2002. In this submission, Able hailed "its significant increase in sales of our recently approved generic drugs resulting in a ... 137% net increase in sales ... as compared to the three months ended March 31, 2001" and that "Able has received FDA approval for 13 new products." At the close of business on or about May 6, 2002, Able's stock traded at approximately $.36 (36

cents) per share.

b. On or about November 9, 2004, Able filed its Form 10-Q with the SEC for the financial quarter which ended on September 30, 2004. In this submission, Able claimed a net sales increase of over 30% from the corresponding period in 2003, which it attributed to "a greater number of products available for sale as well as higher demand for our existing products." Specifically, Able proclaimed the Company now had "28 FDA approved product families, in 73 different strengths, available for sale, compared to 21 FDA approved product families, in 47 different strengths, available for sale as of September 30, 2003." At the close of business on or about November 9, 2004, Able's stock traded at approximately $19.90 per share.

c. On or about March 7, 2005, Able issued a press release representing that the Company's "record sales and earnings for the year," referring to the year ending on or about December 31, 2004, was due to numerous new drug approvals and "increased acceptance of our products ...." At the close of business on or about March 7, 2005, Able's stock traded at over $21 per share.

d. In a press release dated on or about May 5, 2005, Able announced the financial results for the first quarter of 2005, touting an annual net sales increase of 43 percent and a diluted earnings-per-share increase of 140 percent. At the close

of business on or about May 5, 2005, Able traded at over $24 per share.

e. On or about May 10, 2005, in its form 10-Q filed with the SEC for the financial quarter ending on March 31, 2005, Able again represented its substantial increases in sales and profits. Able further noted that the Company "conducted voluntary product recalls" of discrete drug products because of "improper laboratory practices and noncompliance with standard operating procedures ... as part of [the Company's] ongoing efforts to maintain [the Company's] regulatory compliance and the quality and integrity of [the Company's] operations ...." Notwithstanding the disclosures of improprieties and the recalls of products, Able represented in this Form 10-Q that "[a]t this time, we have not experienced a material adverse impact on our business or operations in connection with our ongoing comprehensive review ...." At the close of business on or about May 10, 2005, Able's stock traded at approximately $24.90 per share.

Unlawful Sales of Able Stock

37. As an Officer of Able, defendant **SHAH** and the other trading executives owed fiduciary and other duties to Able and its shareholders to abstain from trading shares of Able stock while in possession of material non-public information.

38. From at least in or around the end of 1999 through on

or about May 19, 2005, defendant **SHAH** and certain of the other trading executives [the "trading co-conspirators"], by virtue of their position at the Company, were entrusted with material, non-public information concerning Able's laboratory practices for testing and monitoring the quality and efficacy of the Company's manufactured generic drug products, and the Company's reporting of the required test results and disclosure of same to the FDA.

39. On various dates from in or around August 2003 through in or around December 2004, defendant **SHAH** and the trading co-conspirators, while in possession of material non-public information, namely, that Able was distributing adulterated and misbranded generic drug products, exercised options that were previously granted to them through the First and Second Trading Plans.

40. Upon entering into the First and Second Trading Plans, defendant **SHAH** and the trading co-conspirators falsely certified that they were not aware of any material nonpublic information concerning Able.

41. On numerous occasions from in or around August 2003 through in or around December 2004, defendant **SHAH** and the trading co-conspirators submitted SEC Form 144s which falsely certified that they did not know of any materially nonpublic adverse information relating to Able's business operations.

42. During the relevant time period of this Information,

while in possession of material non-public information, namely that Able was distributing adulterated and misbranded generic drug products, defendant **SHAH** sold shares of Company stock and reaped substantial profits on or about the dates and in the approximate amounts listed below:

Date of Sale	**No. Shares**	**Purchase Price (Per Share)**	**Sale Price* (Per Share)**	**Profit**
Aug. 6, 2003	1,342	$3.75	$23.46	$26,371
Aug. 6, 2003	1,424	$3.75	$22.01	$25,930
Aug. 7, 2003	2,048	$3.75	$21.27	$35,771
Aug. 8, 2003	1,186	$3.75	$22.00	$21,583
Oct. 2, 2003	6,000	$3.75	$18.24	$86,629
Dec. 1, 2003	6,000	$3.75	$18.61	$88,849
Feb. 2, 2004	10,000	$3.75	$18.12	$143,186
April 1, 2004	10,000	$3.75	$19.38	$155,790
June 1, 2004	5,912	$3.75	$18.42	$86,425
June 2, 2004	4,088	$3.75	$18.40	$59,678
Sept. 1, 2004	5,000	$3.75	$21.73	$89,642
Dec. 1, 2004	5,000	$3.75	$21.63	$89,142

Total Shares Sold: 58,000 Approx. Total Profits: $909,000

43. The trading co-conspirators, and individuals close to them, continued to exercise Company options and sell Able shares through in or around mid-May 2005.

The Disclosure of Improprieties and the Collapse of Able

44. On or about May 19, 2005, the Company issued a press release announcing that the Company had suspended shipments for

its entire generic drug product line because of indications of improper laboratory practices and noncompliance with standard operating procedures. In addition, in a separate press release also issued on or about May 19, 2005, Able announced that its Chairman and Chief Executive Officer had resigned from the Company.

45. On or about May 18, 2005, the day before the announcements, Able traded at its high of over $26 per share, with a daily trading volume of less than 1.1 million shares. At the close of business on or about May 19, 2005, after the announcements, Able's stock plummeted approximately 75 percent from the day before, closing at $6.26 per share, and with a daily trading volume of more than 30 million shares.

46. On or about May 23, 2005, in a Form 8-K filed with the SEC, Able advised that it had issued a nationwide recall for all of its delivered generic drug products. On or about May 27, 2005, the FDA issued a public advisory to consumers regarding Able's nationwide recall.

47. On or about July 28, 2005, Able was delisted as a publicly-traded security on the NASDAQ after the Company filed for bankruptcy under Chapter 11.

Overt Acts

48. In furtherance of the conspiracy and to effect the unlawful objects thereof, defendant **SHAH** and his co-conspirators committed and caused to be committed the following overt acts, among others, in the District of New Jersey and elsewhere:

a. In or around March or April 2003, defendant **SHAH** and other high level Able executives directed and supervised the creation of false and fraudulent entries in chemist Laboratory Notebooks, and in the corresponding Process Validation binders, relating to the Company's ANDA for Lithium Carbonate Extended Release tablets, for which Able received FDA approval on or about April 21, 2003.

b. In or around 2003, defendant **SHAH**, upon the direction of another high level Able executive, supervised the falsification of testing data for Methylphenidate.

c. In or around 2002, defendant **SHAH**, upon the direction of another high level Able executive, supervised the falsification of testing data for Butalbital, Acetaminophen and Caffeine.

d. In or around August 2003, defendant **SHAH** signed the First Trading Plan which falsely certified that he was not aware of any material, nonpublic information concerning the Company's business operations.

e. In or around August 2004, defendant **SHAH** signed the

Second Trading Plan which falsely certified that he was not aware of any material, nonpublic information concerning the Company's operations.

f. On or about August 4, 2003, defendant **SHAH** signed an SEC Form 144 which falsely represented that he had no knowledge of any material, nonpublic information concerning the Company's business operations.

All in violation of Title 18, United States Code, Section 371.

CHRISTOPHER J. CHRISTIE
United States Attorney