

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Hon.
v. : Criminal No.
DILIP PATEL : 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.

Defendant

2. Defendant Dilip Patel ["**PATEL**"] was a resident of

Iselin, New Jersey, and was employed at Able, beginning in or around mid-1998, as a Chemist in the Quality Control ["QC"] Department. In or around April 2002, defendant **PATEL** was promoted to serve as a Supervisor of Analytical Control in the QC Department, and served in that capacity until on or about January 1, 2005, when he was promoted to serve as Quality Control Manager. While at Able, his annual salary increased from approximately \$40,000 to approximately \$85,000.

3. As Supervisor of Analytical Control in the QC Department and Quality Control Manager, defendant **PATEL** was responsible for:

a. supervising numerous chemists who performed analytical quality control tests on Able's manufactured generic drug products which tests were designed to ensure product safety and effectiveness;

b. monitoring the chemists' compliance with current Good Manufacturing Practices ["GMPs"], as required by the United States Food and Drug Administration ["FDA"], and Standard Operating Procedures ["SOPs"] established by the Company; and

c. ensuring compliance with Able's SOPs, including protocols for investigating, logging and archiving any aberrant, deviant or failing analytical laboratory results, commonly referred to by Able as "Out of Specification" ["OOS"] reports.

United States Food and Drug Administration ["FDA"]

4. 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.

5. 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.

6. 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, an applicant was required by the FD&C Act to submit to the FDA an "Abbreviated New Drug Application" ["ANDA"], which included data and information confirming, among other things, that the manufacturer produced product that was consistently equivalent to the innovator product and was safe and effective.

7. 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. Section 352(a).

8. 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 identity, strength, quality, and purity characteristics. 21 U.S.C. Section 351(a)(2)(B).

9. 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 test 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.

10. 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).

11. 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

12. 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. Part 211.

13. 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 CONSPIRACY

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

DILIP PATEL

did knowingly and willfully conspire and agree with others to cause the introduction and delivery for introduction into interstate commerce of a drug that was adulterated and misbranded, with an intent to defraud and mislead, contrary to Title 21, United States Code, Sections 331(a) and 333(a)(2).

The Object of the Conspiracy

15. The principal object of the conspiracy was to create false and fraudulent records and information for the following purposes: (a) obtaining FDA approval to manufacture generic drug products; (b) concealing from the FDA failing quality control test results relating to Able's generic drug products, thereby avoiding seizures of product, recalls of distributed product, and cessation of product deliveries; and (c) enabling continued distribution and delivery of pharmaceutical generic drug products to the general public notwithstanding testing failures.

Means and Methods of the Conspiracy

16. Throughout the conspiracy, defendant **PATEL** 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 below.

17. It was part of the conspiracy that defendant **PATEL** 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.

18. It was further part of the conspiracy that defendant

PATEL and his co-conspirators created and maintained false, fraudulent, and inaccurate data and records to obtain FDA approval to manufacture new product lines and thereby increase the Company's sales and profit.

Overt Act

19. In furtherance of the conspiracy and to effect the unlawful object thereof, defendant **PATEL** 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 mid-2003, upon instructions from K.H., defendant **PATEL** supervised the falsification and manipulation of assay test results for Atenolol, a prescription medication for cardiac conditions.

b. In or around the end of 2004, upon instructions from Shashikant Shah, defendant **PATEL** directed a subordinate chemist to falsify and manipulate dissolution test results for Methylphenidate Hydrochloride Extended-Release Tablets, a prescription medication for attention deficit and hyperactivity.

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

CHRISTOPHER J. CHRISTIE
United States Attorney