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DIS: USAO 2010R00949

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA

v.

CHENG YI LIANG,

Defendant

- * DKC 1 1 CR 253 CRIMINAL NO.
 * (Insider Trading, 15 U.S.C. §§ 78j(b)
 * and 78ff; False Statements, 18 U.S.C.
 * § 1001; Aiding and Abetting, 18 U.S.C.
 * § 2; Forfeiture, 18 U.S.C. § 981(a)(1)(C),
 * 28 U.S.C. § 2461(c))
- **INFORMATION**

COUNT ONE

The United States Attorney for the District of Maryland charges that:

Introduction

At all times relevant to this Information:

A. The FDA's Drug Approval System

1. The FDA was an independent federal agency responsible for, among other things, protecting the public health by assuring the safety, efficacy and security of drugs intended for human use. As part of that responsibility, the FDA established a process for the approval of experimental drugs.

2. The FDA's Center for Drug Evaluation Research ("CDER") regulated over-the-counter and prescription drugs. The Prescription Drug User Fee Act ("PDUFA") required the CDER to review and act upon at least 90 percent of New Drug Applications ("NDAs") for standard drugs no later than ten months after the application is received. The date by which the CDER was required to act is commonly referred to as the "PDUFA date." PDUFA

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dates are publicly known, as the "sponsors" typically announce the dates in press releases and filings.

3. After an NDA was filed and accepted for review, a CDER review team evaluated whether the studies submitted by the sponsor show that the drug is safe and effective for its proposed use. If the CDER determined that the drug was safe, it approved the drug.

4. The FDA's drug reviews were nonpublic. The FDA is prohibited from disclosing that an NDA has been filed, the existence of a review, or that it has issued a complete response letter. The FDA only disclosed information when it approved a new drug.

B. The Defendant and His Access to the FDA DARRTS System

5. Defendant **CHENG YI LIANG** was a citizen of the United States and a resident of Maryland. Beginning on or about October 27, 1996, **CHENG YI LIANG** was a chemist for the FDA, working in the CDER at Office of New Drug Quality Assessment.

6. As part of his duties with the FDA, defendant **CHENG YI LIANG** had access to the FDA's Document Archiving, Reporting and Regulatory Tracking System ("DARRTS") system, which the CDER used internally to manage, track, receive and report on NDAs as well as emerging significant drug safety issues. The DARRTS system is an internal, CDER-only system; a secure password is required to access the system.

7. The DARRTS system allowed defendant **CHENG YI LIANG** to review documents related to the progression of experimental drugs through the FDA new drug approval process, including, among the confidential and non-public documents, results of internal FDA trials and studies, confidential correspondence between FDA representatives and pharmaceutical company representatives, and internal FDA memoranda.

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8. Much of the information accessible on the DARRTS system constituted material, non-public information (the "FDA Inside Information") regarding the pharmaceutical companies which had submitted their experimental drugs to the FDA for approval. FDA employees were also required to submit an annual Form 450 Confidential Financial Disclosure, disclosing, among other things, investment assets with a value greater than \$1000 and sources of income greater than \$200. This form warned on its cover page that "[k]nowing and willful falsification of information required to be reported may also subject you to criminal prosecution."

C. The Defendant's Fiduciary Duty to the FDA

9. The Standards of Ethical Conduct for Employees of the Executive Branch require that "an employee shall not engage in a financial transaction using nonpublic information, nor allow the improper use of nonpublic information to further his own private interest or that of another, whether through advice or recommendation, or by knowing unauthorized disclosure." 5 C.F.R. § 2635.703(a).

D. The Defendant's Financial Disclosure Requirement

FDA employees were required to submit an annual Confidential Financial
 Disclosure Form, disclosing, among other things, investment assets with a value greater than
 \$1000 and sources of income greater than \$200.

The Insider Trading Scheme

11. Between in or about July 2006 and in or about March 2011, in the District of Maryland and elsewhere, the defendant,

CHENG YI LIANG,

did willfully and unlawfully, directly and indirectly, by the use of any means and instrumentality

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of interstate commerce and of the mails, and of any facility of any national securities exchange, use and employ, in connection with the purchase and sale of any security registered on a national securities exchange, manipulative and deceptive devices and contrivances in contravention of rules and regulations prescribed by the Securities and Exchange Commission, including Rule 10b-5 as set forth in 17 CFR 240.10b-5, as necessary and appropriate in the public interest and for the protection of investors ("the insider trading scheme").

B. Manner and Means of the Insider Trading Scheme

12. It was part of the insider trading scheme that defendant **CHENG YI LIANG** learned that on or about May 21, 2010, the FDA accepted Clinical Data, Inc.'s ("Clinical Data") NDA for Viibryd, an antidepressant with the active ingredient Vilazodone. The FDA set a PDUFA date of January 22, 2011, which was publicly announced by Clinical Data in a press release. Clinical Data was a pharmaceutical company whose stock traded on the NASDAQ.

13. It was further part of the insider trading scheme that between on or about January 6, 2011 and on or about January 21, 2011, defendant CHENG YI LIANG regularly accessed the DARRTS system and reviewed information regarding Clinical Data's drug Viibryd.

14. It was further part of the insider trading scheme that defendant **CHENG YI LIANG** used nominee names to create and access numerous trading accounts with brokerage companies like Scottrade, Inc. and TD Ameritrade ("the Controlled Accounts").

15. It was further part of the insider trading scheme that on or about January 18, 2011 between approximately 8:40 a.m. and approximately 5:50 p.m., defendant **CHENG YI LIANG** accessed the DARRTS system at approximately 10:48 a.m., approximately 12:04 p.m., and approximately 5:06 p.m. and reviewed information related to Clinical Data's Viibryd application.

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16. It was further part of the insider trading scheme that on or about January 18, 2011 at approximately 5:06 p.m., defendant **CHENG YI LIANG** reviewed an internal FDA memorandum dated January 18, 2011, which concluded that "I believe the sponsor has submitted sufficient data to support the conclusion that Vilazodone is effective and acceptably safe ... [W]e will forward an approval package to the Office."

17. It was further part of the insider trading scheme that on or about January 18, 2011, defendant **CHENG YI LIANG** accessed several of the Controlled Accounts and purchased and caused to be purchased nearly 10,000 shares of Clinical Data stock.

18. It was further part of the insider trading scheme that between on or about January 6, 2011 and on or about January 21, 2011, defendant **CHENG YI LIANG** used several of the Controlled Accounts to purchase and cause to be purchased a total of approximately 46,875 shares of Clinical Data stock at prices ranging from approximately \$14.70 to approximately \$15.90 per share. After the markets closed on Friday, January 21, 2011, Dow Jones released news of Viibryd's approval. Clinical Data's stock price closed at approximately \$15.03 per share on January 21, 2011 and opened at approximately \$24.76 per share on January 24, 2011, the first trading day after news of the approval became public

19. It was further part of the insider trading scheme that on or about January 24, 2011, defendant **CHENG YI LIANG** used several of the Controlled Accounts to sell a total of approximately 46,875 shares of Clinical Data stock, at prices ranging from approximately \$23.25 to \$23.62 per share. The total profit from these sales was approximately \$379,602.

20. It was further part of the insider trading scheme that between in or about July 2006 and March 2011, defendant CHENG YI LIANG purchased and sold stock in more than 25

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companies, using FDA Inside Information in breach of his duty, and made profits or avoided

losses in the amount of \$3,776,152.

15 U.S.C. §§ 78j(b) and 78ff 17 C.F.R.§ 240.10b-5 18 U.S.C. § 2 Case 8:11-cr-00530-DKC Document 31 Filed 09/26/11 Page 7 of 9

COUNT TWO

The United States Attorney for the District of Maryland further charges that:

1. Paragraphs 1 through 10 and 12 through 20 of Count One are incorporated here.

2. On or about February 16, 2010, in the District of Maryland and elsewhere, the defendant,

CHENG YI LIANG

in a matter within the jurisdiction of the executive branch of the government of the United States, did knowingly and willfully falsify, conceal, and cover up by a trick, scheme or device a material fact, by failing to disclose in his annual Form 450 Confidential Financial Disclosure filed with the FDA that he had traded in the stock of Vanda, a pharmaceutical company.

18 U.S.C. § 1001 18 U.S.C. § 2

FORFEITURE ALLEGATION

The United States Attorney for the District of Maryland further charges that:

1. Pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c), 2253, upon conviction of an offense set forth in Count One of this Information, in violation of 15 U.S.C. §§ 78j(b) (and Rule 10b-5 thereunder, 17 C.F.R. §240.10b-5), 78ff and 18 U.S.C. § 2, defendant **CHENG YI LIANG** shall forfeit to the United States of America any property, real or personal, which constitutes or is derived from proceeds traceable to the insider trading scheme, specifically, a money judgment in the amount of \$3,766,152.

2. If the property described above in paragraph 2 as being subject to forfeiture, as a result of any act or omission of any defendant --

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third person;
- c. has been placed beyond the jurisdiction of the Court;
- d. has been substantially diminished in value; or,
- has been commingled with other property which cannot be subdivided without difficulty;

the United States shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c).

Such substitute property shall include, but is not limited to:

a. All funds, minus any applicable taxes or penalties, in Thrift Savings Plan account number 1101 9366 53848, in the name of the defendant **CHENG**

YI LIANG.

18 U.S.C. § 981(a)(1)(C) 28 U.S.C. § 2461(c)

Rod J. Rosenstein

United States Attorney

Denis J. McInerney Chief, Fraud Section Criminal Division United States Department of Justice

9/26/2011 Date