IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

UNITED STATES OF AMERICA, Plaintiff, v. LISA SHARP, and WAYNE SPENCER, M.D., Defendants.	)	No. 11-40042-01-02-RDR Count 1: 18 U.S.C. § 371 Counts 2-4: 18 U.S.C. § 1341 Count 5: 21 U.S.C. § 331(e) Counts 1-5: 18 U.S.C. § 2

INDICTMENT

The Grand Jury charges:

At all material times:

INTRODUCTION

1. From in or about January, 2010, through in or about May, 2010, defendants **LISA SHARP** and **WAYNE SPENCER, M.D.**, while employed at Lee Research Institute, were involved in a conspiracy and scheme to defraud Schering/Plough, a subsidiary of Merck ("Schering/Plough") in relation to a clinical drug trial. Specifically, defendants falsified study data to remain in the clinical drug trial and receive monies from Schering/Plough.

2. Schering/Plough was a pharmaceutical company engaged in developing, testing, and marketing pharmaceutical products, including a sublingual

tablet developed for the treatment of allergies, namely ragweed-induced rhino conjunctivitis.

3. Under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, Schering/Plough, the drug sponsor, had to apply to the United States Food and Drug Administration ("FDA"), an agency of the United States, for approval to market their sublingual tablet. As a drug sponsor, Schering/Plough was required to demonstrate, through clinical investigations, the safety and effectiveness of the sublingual tablet before the FDA would approve it for human use or consumption. Clinical investigations are experiments or studies in which the sublingual tablet was administered to a human group. The FDA examines the results, design, and conduct of the clinical studies in deciding whether the sublingual tablet should be approved for marketing.

4. Before beginning the clinical study, the FDA required Schering/Plough to provide the FDA a detailed investigation plan known as the "study protocol." The study protocol contained information about how the clinical study would be conducted, where studies would be done and by whom, how the drug's safety would be evaluated, and what findings would require the study to be changed or halted.

5. Schering/Plough hired clinical investigators to carry out the actual clinical studies of the drug on human subjects. Participating clinical investigators signed FDA Forms 1572, committing to conduct the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations. The FDA required that truthful and correct information be provided in order to evaluate the safety and performance of a drug before it approved the drug's use by certain groups of individuals.

6. In or about July 2009, Schering/Plough chose Lee Research Institute to perform a clinical study known as "A 28-Day Study Evaluating the Safety of Ragweed (*Ambrosia artemisiifolia*) Sublingual Tablet (SCH 39641) in Adult Subjects 50 years of age and Older with Ragweed-Induced Rhino conjunctivitis" ("the clinical study").

7. Defendant **WAYNE SPENCER, M.D.**, a licensed medical doctor practicing medicine in the District of Kansas, was the Principal Investigator for the clinical study.

8. Defendant **LISA SHARP** was the Lead Clinical Research Coordinator for the clinical study. Additionally, defendant **LISA SHARP** was the Director of Clinical Trials for Lee Research Institute.

9. Defendants **LISA SHARP** and **WAYNE SPENCER, M.D.**, agreed to conduct the study in strict compliance with the criteria set forth in the study protocol.

10. According to Section 7.3.1 of the study protocol, "each subject must be 50 years of age and older."

11. According to Section 7.3.2 of the study protocol, "a subject who is a member or a family member of the personnel of the investigational or sponsor staff directly involved with this trial" are excluded from the study. In other words, employees of Lee Research Institute were excluded from the study.

12. The clinical study required that Lee Research Institute enroll eight eligible participants.

COUNT 1 – CONSPIRACY

13. The Grand Jury incorporates by reference Paragraphs 1 through 12 as though fully restated and re-alleged herein.

14. From in or about January 2010, through in or about May 2010, the exact dates being unknown to the Grand Jury, in the District of Kansas, the defendants

LISA SHARP
and
WAYNE SPENCER, M.D.,

knowingly and willfully combined, conspired, confederated, and agreed with each other and with others, both known and unknown to the Grand Jury:

(a) to commit mail fraud, in violation of Title 18, United States Code, Section 1341;

(b) to violate the Food, Drug and Cosmetic Act by failing to prepare and maintain records required under 21 U.S.C. § 355(i) and 21 C.F.R. § 312.62(b), with intent to defraud and mislead, in violation of Title 21, United States Code, Section 331(e); and

(c) to defraud the United States and departments and agencies thereof, namely, the Food and Drug Administration, by impairing, impeding and obstructing by craft, trickery, deceit, and dishonest means, its lawful and legitimate function of regulating drugs.

Purpose of the Conspiracy and Scheme

15. A purpose of the conspiracy and scheme was to make money for Lee Research Institute, the defendants' employer, so that Lee Institute would remain in business and the defendants would remain employed.

Manner and Means

16. Defendants **LISA SHARP** and **WAYNE SPENCER, M.D.**, and others used the following manner and means in furtherance of the continuing

conspiracy and scheme to defraud. In so doing, defendants **LISA SHARP** and **WAYNE SPENCER, M.D.**, and others, at times, used and perverted lawful conduct to further the conspiracy and scheme.

17. It was a part and object of the continuing conspiracy and scheme to defraud that defendants **LISA SHARP** and **WAYNE SPENCER, M.D.**, reported that all eight study subjects for the clinical study were qualified to participate in the study, when they knew that two subjects were not qualified because of age and employment.

18. It was a part and object of the continuing conspiracy and scheme to defraud that defendant **LISA SHARP,** in direct violation of the protocol, had two employees at Lee Research Institute, namely the Regulatory Coordinator and another Clinical Research Coordinator, complete enrollment forms to be clinical study participants using the false names of Kathryn F. Cline and Elizabeth S. Armstrong.

19. It was a part and object of the continuing conspiracy and scheme to defraud that defendant **LISA SHARP,** in direct violation of the protocol, had two employees at Lee Research Institute, namely the Regulatory Coordinator and another Clinical Research Coordinator, enroll as clinical study participants, even though both were under the age of 50. Defendant **LISA SHARP** provided the

employees with false birth years to use for the enrollment forms and to make it appear that they met the protocol requirement of being 50 years of age or older.

20. It was a part and object of the continuing conspiracy and scheme to defraud that defendant **LISA SHARP** approved payments to the two employees for participating in the clinical study.

21. It was a part and object of the continuing conspiracy and scheme to defraud that defendants **LISA SHARP** and **WAYNE SPENCER, M.D.**, knowing that two employees were falsely enrolled in the clinical study, signed multiple forms and records, all of which were documents required to be created and maintained as a part of the clinical study.

Overt Acts

22. In furtherance of the continuing conspiracy and scheme to defraud, and to accomplish their purposes and objectives, one or more of the co-conspirators committed in the District of Kansas the following overt acts, among others:

a. Each of the allegations set forth in Counts 2-5 is incorporated and realleged as though restated herein, as an individual overt act done in furtherance of the conspiracy.

b. On or about January 8, 2010, two Lee Research Institute employees enrolled as participants in the clinical study under false names and using false dates of birth. Neither employee was 50 years of age or older.

c. On or about January 8, 2010, defendant **LISA SHARP** informed defendant **WAYNE SPENCER, M.D.**, that two employees had enrolled as participants in the clinical study.

d. On or about January 8, 2010, defendant **WAYNE SPENCER, M.D.**, signed multiple documents for the enrolled employees, including page 6 of the Screen Visit Forms, indicating that he had performed physical examinations on the two employees, when he had not performed any physical examinations of these two employees.

e. On or about January 8, 2010, defendant **LISA SHARP** signed multiple documents for the enrolled employees, including documents that falsely stated their dates of birth.

f. On or about January 11, 2010, defendant **WAYNE SPENCER, M.D.**, signed page 5 of the Screen Visit Forms for both enrolled employees, indicating that the patients met the inclusion/exclusion criteria, when he knew that they did not.

g. On or about February 22, 2010, defendant **WAYNE SPENCER, M.D.**, signed FDA Form 1572, indicating that he had conducted the clinical study in accordance with the protocol.

h. During the course of the clinical study, defendant **LISA SHARP** made sure that the two employees had office visits when the Executive Director was at lunch, to conceal from her the fact that the clinical study had two ineligible participants.

23. The foregoing is in violation of Title 18, United States Code, Sections 371 and 2.

COUNTS 2-4

24. The Grand Jury incorporates by reference Paragraphs 1 through 23 as though fully restated and re-alleged herein.

25. On or about the dates detailed below, in the district of Kansas, defendants

LISA SHARP
and
WAYNE SPENCER, M.D.

knowingly and intentionally devised a scheme to defraud, and for the purpose of executing the scheme to defraud, and attempting to do so, deposited and caused to be deposited in any post office or authorized depository for mail matter, any matter

or thing whatever to be sent or delivered by the Postal Service, and deposited and caused to be deposited any matter or thing whatever to be sent or delivered by any private or commercial interstate carrier, and took and received from the Postal Service and any private or commercial interstate carrier any such matter or thing, namely the following checks issued to Lee Research Institute in payment for the clinical study:

Count	On or about Date	Check Number	Amount
2	February 26, 2010	4628769	20,877.00
3	April 9, 2010	4639491	7,606.80
4	May 10, 2010	4645963	3,604.80

26. The foregoing is in violation of Title 18, United States Code, Sections 1341 and 2.

COUNT 5 – FDCA VIOLATION

27. The Grand Jury incorporates by reference Paragraphs 1 through 23 as though fully restated and re-alleged herein.

28. FDA regulations imposed the following specific responsibilities on defendants **LISA SHARP** and **WAYNE SPENCER, M.D.**, in regards to the clinical study: to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the

investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

29. The study protocol also imposed specific responsibilities on defendants **LISA SHARP** and **WAYNE SPENCER, M.D.**, in regards to the clinical study. The defendants were required to:

a. maintain records and data during the trial in compliance with all applicable legal and regulatory requirements; and

b. maintain source documents that support each data point, and retain such source documents for review by the sponsor or a regulatory agency.

30. Under Title 21, United States Code, Section 331(e), it is unlawful for any person, with intent to defraud and mislead, to fail to establish or maintain any record, or make any report required under Title 21, United States Code, Section 355(i), including those records required under 21 C.F.R. §§ 312.62(b) and 312.66.

31. Beginning in or about January 2010, and continuing through in or about May 2010, in the district of Kansas, defendants

LISA SHARP
and
WAYNE SPENCER, M.D.,

with intent to defraud and mislead, failed to prepare and maintain records required under 21 U.S.C. § 355(i) and 21 C.F.R. § 312.62(b), namely, adequate and accurate case histories on each individual administered the investigational drug, in that the defendants falsified the birth dates of two participants; falsely indicated that physical examinations had been performed, when they had not been performed; and indicated on required forms that the two participants met the inclusion criteria and had no reasons for exclusion, when the defendants knew that the participants did not meet the inclusion criteria of age and should have been excluded as employees of the research facility conducting the clinical study.

32. The foregoing is in violation of Title 21, United States Code, Section 331(e), 333(a)(2), and Title 18, United States Code, Section 2.

A TRUE BILL.

Dated: June 1, 2011

s/ Foreperson
FOREPERSON

Tanya J. Treadway #13255
BARRY R. GRISSOM
United States Attorney
District of Kansas
500 State Avenue, Suite 360
Kansas City, KS 66101
913-551-6730
913-551-6541 (fax)
barry.grissom@usdoj.gov
Ks. S. Ct. # 10866

(It is requested that trial of the above captioned case be held in Topeka, Kansas.)