

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

FILED

JUL 23 2020

CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF OHIO
CLEVELAND

UNITED STATES OF AMERICA,

Plaintiff,

v.

AMIE DEMMING,
JOHN PANUTO,
DEBRA ADAMSON,
ASHLEY NICHOLE ADAMSON,
WILLIAM ADAMSON,
DANIEL GWIN,
BRENT SMITH,
WALTER O'MALLEY,

Defendants.

) INDICTMENT

) 1:20 CR 395

) CASE NO.

) Title 18, United States Code,
) Sections 371, 1028A(a)(1),
) 1341, 1343, 1349, and 2;
) Title 21, United States Code,
) Sections 331(e), 333(a)(2), and
) 355(i); Title 21, Code of Federal
) Regulations, Section 312.62(b)

JUDGE LIOI

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

I. Defendants and Other Entities

1. Company 1 was a research organization that conducted clinical trials of investigational drugs for pharmaceutical sponsors. Company 1 was formed in or around December 2008 by AMIE DEMMING and DEBRA ADAMSON and had office locations in Ohio and Tennessee. Company 1's principal place of business in Ohio, from its inception through in or around 2013, was JOHN PANUTO's office. From in or around 2013 through in or around December 2016, Company 1's principal place of business in Ohio was located at 6900 Pearl Road, Suite 305, Middleburg Heights, Ohio (collectively, the "Middleburg Heights Office"). Company 1's principal place of business in Franklin, Tennessee was located at 4601 Carothers Parkway, Suite 350, Franklin, Tennessee (the "Franklin Office"). Company 1's

principal place of business in Smyrna, Tennessee was located at 515 Stonecrest Parkway, Suite 110, Smyrna, Tennessee (the "Smyrna Office").

2. Defendant AMIE DEMMING ("DEMMING") was a Certified Clinical Research Coordinator and resident of Strongsville, Ohio. From on or about December 28, 2008, through on or about November 10, 2016, DEMMING was President of Company 1. DEMMING worked out of the Middleburg Heights Office and was responsible for the management of that office. DEMMING, along with DEBRA ADAMSON, controlled the daily operations of Company 1.

3. Defendant JOHN PANUTO ("PANUTO") was a medical doctor licensed by the State of Ohio Medical Board on or about January 16, 1990. PANUTO specialized in allergy and immunology. PANUTO's primary practice location was 15299 East Bagley Road, Suite 300, Middleburg Heights, Ohio. PANUTO was the Principal Investigator for Company 1 at the Middleburg Heights Office and was responsible for the oversight of most clinical trials conducted at that office. Additionally, from on or about February 5, 2014, through on or about February 3, 2016, PANUTO received \$1,200 per month as the purported Medical Director of Company 1.

4. Defendant DEBRA ADAMSON ("DEBRA ADAMSON") was a resident of Spring Hill, Tennessee. From on or about January 1, 2009, through on or about October 15, 2017, DEBRA ADAMSON was the Vice President of Clinical Operations at Company 1. DEBRA ADAMSON worked out of the Franklin Office and was responsible for the management of that office. Along with DEMMING, DEBRA ADAMSON controlled the daily operations of Company 1. DEBRA ADAMSON was DEMMING's mother.

5. Defendant ASHLEY NICHOLE ADAMSON ("ASHLEY ADAMSON") was a resident of Thompsons Station, Tennessee. From on or about March 1, 2011, through on or

about August 21, 2017, ASHLEY ADAMSON was the Site Manager at the Smyrna Office and was responsible for the management of that office. ASHLEY ADAMSON was DEMMING's sister-in-law.

6. Defendant WILLIAM ADAMSON ("WILLIAM ADAMSON") was a resident of Thompsons Station, Tennessee. From on or about March 5, 2010, through on or about June 9, 2017, WILLIAM ADAMSON was the Site Manager at the Franklin Office and, along with DEBRA ADAMSON, was responsible for the management of that office. WILLIAM ADAMSON was DEMMING's brother.

7. Defendant DANIEL GWIN ("GWIN") was a resident of Cleveland, Ohio. From on or about June 1, 2013, through on or about December 6, 2016, GWIN was the Study Coordinator at the Middleburg Heights Office and was responsible for coordinating clinical investigations at that office.

8. Defendant BRENT SMITH ("SMITH") was a resident of Cleveland, Ohio. From on or about February 4, 2013, through on or about February 28, 2017, SMITH was the Data Manager/Information Technology Specialist for Company 1 at the Middleburg Heights Office.

9. Defendant WALTER O'MALLEY ("O'MALLEY") was a resident of Cleveland, Ohio. O'MALLEY was the romantic partner of DEMMING and was not an employee of Company 1.

10. The United States Food and Drug Administration ("FDA") was the agency of the United States responsible for, among other things, enforcing the provisions of the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Section 301 *et seq.* The FDA was responsible for ensuring that drugs intended for use in humans were safe and effective for their

intended uses. The FDA was also responsible for ensuring that clinical investigations of human drugs were conducted ethically and to minimize patient harm.

11. Sponsor 1, Sponsor 2, Sponsor 3, Sponsor 4, Sponsor 5, Sponsor 6, Sponsor 7 and Sponsor 8 (collectively, the “Sponsors”) were pharmaceutical companies engaged in developing, testing, and marketing pharmaceutical products intended for use in humans.

II. Background on FDA Clinical Trials

12. The Federal Food, Drug, and Cosmetic Act and its implementing regulations required trial sponsors—in this case, pharmaceutical manufacturers—to submit an Investigational New Drug Application (“IND”) to the FDA before conducting a clinical investigation with an investigational new human drug. With certain narrow exemptions, trial sponsors could not begin a clinical investigation until the investigation was subject to an IND.

13. Before commencing any clinical investigation, trial sponsors were required to provide the FDA with extensive information regarding the proposed study, including a detailed investigation plan known as the “study protocol.” The study protocol contained information about how the clinical investigation or study would be conducted, where the study would be conducted, by whom, how the drug’s safety would be evaluated and what findings would require the study to be changed or halted.

14. Trial sponsors hired qualified physicians, known as principal or clinical investigators, to conduct the actual clinical studies of the drug on human subjects or enrollees. Before permitting an investigator to participate in an investigation, the trial sponsor was required to obtain, among other documentation, a signed Statement of Investigator, FDA Form 1572 (“FDA Form 1572”). The FDA Form 1572 required investigators to abide by the terms of the

study protocol and applicable FDA regulations and warned that a willfully false statement was a criminal offense. The investigators were required to agree, among other obligations:

- a. To conduct the study in accordance with the relevant, current protocol set forth in the study protocol;
- b. To personally conduct or supervise the investigation;
- c. To ensure that the requirements relating to obtaining informed consent were met;
- d. To ensure that all associates, colleagues, and employees assisting the conduct of the study were informed of their obligations to meet these commitments; and
- e. To maintain adequate and accurate records.

15. During the course of an investigational drug study and in accordance with the study protocol, investigators physically administered the study drug to the subjects or enrollees. Although the study enrollees were volunteers, trial sponsors did not necessarily allow all willing volunteers to participate in a given clinical study. Whether an individual could participate depended on whether that individual met certain criteria set forth in the approved study protocol and was based, in part, on the drug under investigation.

16. Investigators were required to prepare and maintain records relating to a clinical investigation. These records included adequate records of the disposition of the investigational drug, including dates, quantity, and use by subject. These records also included adequate and accurate case histories that recorded all observations and other data pertinent to the investigation on each subject administered the investigational drug. Case histories included case report forms and supporting data such as signed and dated consent forms and medical records.

17. Upon completion of a drug study, investigators provided the information about each subject/enrollee, including his/her medical history, his/her laboratory results, and his/her reaction to the drug under study, to the trial sponsor. The trial sponsor then provided the information to the FDA for use in its evaluation of whether the drug should be approved for human use as safe and effective for its intended use.

III. Clinical Trials at Company 1

18. Generally, Company 1 entered into a Clinical Trial Agreement (“CTA”) or similar agreement with a Sponsor, which set forth the study protocol and the qualifying parameters for the study subjects. In conjunction with the CTA, the Principal Investigator (“PI”) responsible for conducting the clinical trial on behalf of Company 1 also signed an FDA Form 1572. Per the CTA, in addition to other fees, the Sponsors paid Company 1 for each participating study subject who satisfied study parameters and completed all required physician visits. Depending on the particular study, the Sponsors paid Company 1 anywhere between approximately \$4,952.75 and \$32,875.00 for each successful study subject.

19. Company 1, in turn, paid individual study subjects for participating in the clinical investigations through “ClinCards,” which were prepaid, reloadable debit cards issued to the study subject. Company 1, through DEMMING and DEBRA ADAMSON, instructed a third party vendor to deposit a certain amount of money onto the subject’s ClinCard as the subject participated in each phase of the study. Depending on the particular study, a study subject was paid anywhere between approximately \$25 and \$500 per office visit for participating in a clinical investigation and received between approximately \$390 and \$1,800 for successfully completing a clinical investigation.

20. On or about December 7, 2012, Company 1 entered into a CTA with Sponsor 1 related to Sponsor 1's Study A, which was a clinical study designed to evaluate the safety and pharmacokinetics of an investigational drug in adults diagnosed with uncomplicated influenza ("Sponsor 1 Study A"). Company 1 conducted Sponsor 1 Study A at its Franklin Office, among other locations. The Exclusion Criteria for Sponsor 1 Study A provided, in part: "A subject will be excluded from the study if there is evidence of the following: . . . [i]s employed by or is related to an employee of the clinical study site."

21. On or about October 15, 2013, Company 1 entered into a CTA with Sponsor 1 related to Sponsor 1's Study B, which was a clinical study designed to evaluate the safety and efficacy of an investigational drug in adults with uncomplicated influenza ("Sponsor 1 Study B"). Company 1 conducted Sponsor 1 Study B at its Franklin Office, among other locations. The Exclusion Criteria for Sponsor 1 Study B provided, in part: "A subject will be excluded from the study if there is evidence of the following: . . . [i]s employed by or is related to an employee of the clinical study site."

22. On or about April 2, 2014, Company 1 entered into a CTA with Sponsor 2 related to Sponsor 2's Study, which was a clinical study designed to establish the equivalence of two investigational drugs when administered by inhalation in patients with asthma ("Sponsor 2 Study"). Company 1 conducted Sponsor 2 Study at its Middleburg Heights Office.

23. On or about August 19, 2014, Company 1 entered into a Task Order Agreement with Sponsor 3 related to Sponsor 3's Study, which was a clinical study designed to evaluate the use of multiple antiviral medications to treat influenza ("Sponsor 3 Study"). Company 1 conducted Sponsor 3 Study at its Middleburg Heights and Franklin Offices, among other locations.

24. On or about October 7, 2014, Company 1 entered into a CTA with Sponsor 4 related to Sponsor 4's Study, which was a clinical study designed to evaluate the safety and efficacy of an investigational drug in the treatment of iron deficient patients with fibromyalgia ("Sponsor 4 Study"). Company 1 conducted Sponsor 4 Study at its Franklin Office. The Inclusion Criteria for Sponsor 4 Study required that a study participant satisfy, among other requirements, the following: "Fibromyalgia diagnosis based on [t]he 2011 modification of the American College of Rheumatology (ACR)'s 2010 preliminary criteria for diagnosing fibromyalgia."

25. On or about February 11, 2015, Company 1 entered into a CTA with Sponsor 5 related to Sponsor 5's Study, which was a clinical study designed to compare the safety and efficacy of two dose levels of an investigational drug versus placebo in moderate to severe adult asthmatic patients at risk of loss of asthma control due to presumptive Human Rhinovirus infection ("Sponsor 5 Study"). Company 1 conducted Sponsor 5 Study at its Middleburg Heights Office.

26. On or about June 8, 2015, Company 1 entered into a CTA with Sponsor 6 related to Sponsor 6's Study, which was a clinical study designed to evaluate the safety and efficacy of an investigational drug for patients with persistent asthma ("Sponsor 6 Study"). Company 1 conducted Sponsor 6 Study at its Middleburg Heights Office. The Exclusion Criteria for Sponsor 6 Study excluded study participants if, among other reasons: "Patient [was] the Investigator or any Sub-Investigator, research assistant, pharmacist, study coordinator, other staff or relative thereof directly involved in the conduct of the study."

27. On or about June 17, 2015, Company 1 entered into a CTA with Sponsor 7 related to Sponsor 7's Study, which was a clinical study designed to evaluate the clinical bioequivalence

of two investigational drugs for the treatment of asthma ("Sponsor 7 Study"). Company 1 conducted Sponsor 7 Study at its Middleburg Heights and Smyrna offices. The Exclusion Criteria for Sponsor 7 Study provided, in part: "Subjects are not eligible if they meet *any* of the following criteria: . . . Have an affiliation with the participating site; in other words, subject may not be an immediate family member of any study site staff and may not be employed directly or indirectly by the study site."

28. On or about November 12, 2015, Company 1 entered into a CTA with Sponsor 8 related to Sponsor 8's Study, which was a clinical study designed to evaluate the safety and efficacy of an investigational drug for patients with persistent asthma ("Sponsor 8 Study"). Company 1 conducted Sponsor 8 Study at its Middleburg Heights office. The Exclusion Criteria for Sponsor 8 Study provided, in part: "A subject will not be eligible for this study if he/she is an immediate family member of the participating investigator, sub-investigator, study coordinator, or employee of the participating investigator."

IV. FDA Inspection of Company 1

29. From on or about October 25, 2017, through on or about December 6, 2017, in response to a complaint by Sponsor 8, an FDA investigator conducted an on-site inspection of PANUTO and Company 1 at the Middleburg Heights office (the "FDA Inspection"). The FDA Inspection initially focused on the Sponsor 8 Study and was expanded to include the Sponsor 6 Study.

30. On or about December 6, 2017, at the close of the FDA Inspection, the FDA issued to PANUTO an FDA Form 483, which contained the FDA's observations concerning the inspection. Among other things, the FDA observed:

- a. Observation 1: that PANUTO did not conduct the Sponsor 8 Study in accordance with the signed statement of investigator and investigational plan;
- b. Observation 2: that PANUTO did not have adequate drug disposition records with respect to quantity and use by subjects in the Sponsor 6 Study; and
- c. Observation 3: that PANUTO failed to prepare or maintain adequate case histories with respect to observations and data pertinent to the Sponsor 6 Study and the Sponsor 8 Study.

COUNT 1

(Conspiracy to Commit Mail Fraud and Wire Fraud, 18 U.S.C. § 1349)

The Grand Jury charges:

31. The factual allegations contained in Paragraphs 1 through 30 are re-alleged and incorporated as though fully set forth herein.

32. From in or around January 2013 through in or around March 2018, the exact dates being unknown to the Grand Jury, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendants AMIE DEMMING, JOHN PANUTO, DEBRA ADAMSON, ASHLEY NICHOLE ADAMSON, WILLIAM ADAMSON, DANIEL GWIN, BRENT SMITH and WALTER O'MALLEY did knowingly and intentionally combine, conspire, confederate and agree with each other, and with others both known and unknown to the Grand Jury, to commit federal offenses, that is, to devise and intend to devise a scheme and artifice to defraud the Sponsors, and to obtain money and property from the Sponsors by means of false and fraudulent pretenses, representations and promises, and for the purpose of executing and attempting to execute the scheme and artifice to defraud:

- a. placed, and caused to be placed, in any depository for mail matter, any matter and thing to be sent and delivered by the Postal Service, and took and received

from the Postal Service, any such matter and thing delivered by the Postal Service, in violation of Title 18, United States Code, Section 1341 (Mail Fraud); and

b. caused to be transmitted by means of wire communication in interstate commerce, writings, signs, signals, pictures and sounds, in violation of Title 18, United States Code, Section 1343 (Wire Fraud).

OBJECTS OF THE CONSPIRACY

33. The objects of the conspiracy were to: (1) induce the Sponsors to engage Company 1 to conduct clinical trials; (2) use false and fraudulent pretenses to defraud the Sponsors; (3) prevent detection of the conspiracy; and (4) enrich the conspirators and others.

MANNER AND MEANS OF THE CONSPIRACY

34. It was part of the conspiracy that:

a. Defendants and their co-conspirators agreed with the Sponsors to conduct clinical trials of investigational drugs according to the terms of the study protocol and applicable FDA regulations.

b. Defendants and their co-conspirators used multiple methods to fraudulently enroll subjects in clinical trials, including that:

i. Defendants and their co-conspirators enrolled, and caused others to enroll, in clinical trials under false or fictitious names.

ii. Defendants and their co-conspirators used past subjects' names and other means of personal identifying information, without their knowledge, to enroll past subjects in studies in which they did not in fact participate.

iii. Defendants and their co-conspirators enrolled, and caused others to enroll, in investigational studies despite not meeting inclusion parameters set forth in study protocols.

c. Defendants and their co-conspirators fabricated and falsified, and caused others to fabricate and falsify, medical records, informed consent forms, and other documentation for the fictitious study subjects.

d. Defendants and their co-conspirators submitted to, and caused others to submit to, medical tests for the fictitious study subjects.

e. Defendants and their co-conspirators submitted and caused the submission of false, fictitious and misleading case histories, medical records, informed consent forms, and other documentation to the Sponsors and, in turn, the FDA.

f. By creating fictitious and fraudulent enrolled study subjects, Defendants and their co-conspirators enriched themselves in at least two ways:

i. Defendants and their co-conspirators caused the Sponsors to make payments to Company 1 for the fictitious and fraudulently enrolled subjects, which increased Company 1's profitability and Defendants' compensation.

ii. Defendants and their co-conspirators caused Company 1 to issue ClinCards for the fictitious and fraudulently enrolled subjects, which Defendants and their co-conspirators then appropriated for the benefit of themselves and others.

ACTS IN FURTHERANCE OF THE CONSPIRACY

35. In furtherance of the conspiracy and to achieve its objectives, one or more members of the conspiracy committed the following acts in furtherance, among others, in the Northern District of Ohio, Eastern Division, and elsewhere:

I. Sponsor 1 Study A

36. On or about December 7, 2012, DEMMING signed a CTA with Sponsor 1 in connection with Sponsor 1 Study A.

A. Study Subjects

37. On or about January 6, 2013, “Suzie D. Copeland,” the surname for whom was the maiden name of DEBRA ADAMSON, was enrolled as Subject Number 238016 in Sponsor 1 Study A.

38. On or about January 6, 2013, ASHLEY ADAMSON signed an informed consent form certifying that she obtained informed consent from “Suzie D. Copeland” to participate in Sponsor 1 Study A.

39. On or about January 9, 2013, “Nichole A. Bockman,” the surname for whom was the maiden name of ASHLEY ADAMSON, was enrolled as Subject Number 238019 in Sponsor 1 Study A using the correct date of birth and social security number for ASHLEY ADAMSON.

40. On or about January 9, 2013, DEBRA ADAMSON signed an informed consent form certifying that she obtained informed consent from “Nichole A. Bockman” to participate in Sponsor 1 Study A.

41. On or about January 11, 2013, “Hank W. Bobart” was enrolled as Subject Number 238026 in Sponsor 1 Study A using the correct date of birth, social security number and previous address for WILLIAM ADAMSON.

42. On or about January 11, 2013, WILLIAM ADAMSON signed an informed consent form certifying that he obtained informed consent from "Hank W. Bobart" to participate in Sponsor 1 Study A.

B. ClinCard Payments

43. On or about the dates listed below, DEMMING, DEBRA ADAMSON, ASHLEY ADAMSON and WILLIAM ADAMSON caused Company 1 to issue ClinCards, which DEMMING approved, in the names and for the amounts listed below, as payment for participation in Sponsor 1 Study A, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
a	January 7, 2013	\$125.00	DEBRA ADAMSON	DEMMING	Day 1
b	January 8, 2013	\$125.00	DEBRA ADAMSON	DEMMING	Day 2
c	January 8, 2013	\$125.00	DEBRA ADAMSON	DEMMING	Day 3
d	January 10, 2013	\$125.00	DEBRA ADAMSON	DEMMING	Day 4
e	January 12, 2013	\$125.00	DEBRA ADAMSON	DEMMING	Day 5
f	January 12, 2013	\$250.00	DEBRA ADAMSON	DEMMING	Day 6 & 7
g	January 13, 2013	\$125.00	DEBRA ADAMSON	DEMMING	Day 8
h	January 17, 2013	\$150.00	DEBRA ADAMSON	DEMMING	Days 9-14
i	January 22, 2013	\$125.00	DEBRA ADAMSON	DEMMING	Day 15 (Study Term)
j	December 23, 2013	\$25.00	DEBRA ADAMSON	DEMMING	Manual Payment: \$30.00 Weekly contest winner
k	January 9, 2013	\$125.00	ASHLEY ADAMSON	DEMMING	Day 1
l	January 10, 2013	\$125.00	ASHLEY ADAMSON	DEMMING	Day 2
m	January 11, 2013	\$125.00	ASHLEY ADAMSON	DEMMING	Day 3
n	January 12, 2013	\$125.00	ASHLEY ADAMSON	DEMMING	Day 4

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
o	January 13, 2013	\$125.00	ASHLEY ADAMSON	DEMMING	Day 5
p	January 14, 2013	\$250.00	ASHLEY ADAMSON	DEMMING	Day 6 & 7
q	January 15, 2013	\$125.00	ASHLEY ADAMSON	DEMMING	Day 8
r	January 16, 2013	\$150.00	ASHLEY ADAMSON	DEMMING	Days 9-14
s	January 17, 2013	\$125.00	ASHLEY ADAMSON	DEMMING	Day 15 (Study Term)
t	February 5, 2013	\$150.00	ASHLEY ADAMSON	DEMMING	Manual Payment: \$150.00 Jan. 24-29 EDC at home EDC entry
u	January 11, 2013	\$125.00	WILLIAM ADAMSON	DEMMING	Day 1
v	January 12, 2013	\$125.00	WILLIAM ADAMSON	DEMMING	Day 2
w	January 13, 2013	\$125.00	WILLIAM ADAMSON	DEMMING	Day 3
x	January 15, 2013	\$125.00	WILLIAM ADAMSON	DEMMING	Day 4
y	January 15, 2013	\$125.00	WILLIAM ADAMSON	DEMMING	Day 5
z	January 17, 2013	\$250.00	WILLIAM ADAMSON	DEMMING	Day 6 & 7
aa	January 17, 2013	\$125.00	WILLIAM ADAMSON	DEMMING	Day 8
bb	January 17, 2013	\$125.00	WILLIAM ADAMSON	DEMMING	Day 8
cc	January 21, 2013	\$150.00	WILLIAM ADAMSON	DEMMING	Days 9-14
dd	January 21, 2013	\$125.00	WILLIAM ADAMSON	DEMMING	Day 15 (Study Term)

C. Payments to Company 1

44. On or about the dates listed below, DEMMING, DEBRA ADAMSON, ASHLEY ADAMSON and WILLIAM ADAMSON caused Sponsor 1 to pay Company 1, in the manner and the amounts listed below, for participation in Sponsor 1 Study A, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
a	January 29, 2013	\$51,438.75
b	March 1, 2013	\$250,000.00
c	April 15, 2013	\$62,253.75
d	May 20, 2013	\$36,562.50
e	June 3, 2013	\$360,067.78

II. Sponsor 1 Study B

45. On or about October 15, 2013, DEBRA ADAMSON signed a CTA with Sponsor 1 in connection with Sponsor 1 Study B.

A. Study Subjects

46. On or about June 23, 2014, "Margie Rene Williams" was enrolled as Subject Number 0002 in Sponsor 1 Study B using the correct date of birth and social security number for M.E. (an employee of Company 1 at the Franklin Office).

47. On or about June 23, 2014, WILLIAM ADAMSON signed an informed consent form certifying that he obtained informed consent from "Margie Rene Williams" to participate in Sponsor 1 Study B.

48. On or about August 4, 2014, "Nichole A. Bockman," the surname for whom was the maiden name of ASHLEY ADAMSON, was enrolled as Subject Number 0004 in Sponsor 1 Study B using the correct date of birth and address for ASHLEY ADAMSON.

49. On or about August 4, 2014, WILLIAM ADAMSON signed an informed consent form certifying that he obtained informed consent from "Nichole A. Bockman" to participate in Sponsor 1 Study B.

50. On or about December 6, 2014, "Suzy A. Copeland," the surname for whom was the maiden name of DEBRA ADAMSON, was enrolled as Subject Number 0018 in Sponsor 1 Study B using the correct date of birth and social security number for DEBRA ADAMSON.

51. On or about December 6, 2014, M.E. signed an informed consent form certifying that she obtained informed consent from “Suzy A. Copeland” to participate in Sponsor 1 Study B.

B. ClinCard Payments

52. On or about the dates listed below, DEMMING, DEBRA ADAMSON, ASHLEY ADAMSON and WILLIAM ADAMSON caused Company 1 to issue ClinCards, which DEMMING approved, in the names and for the amounts listed below, as payment for participation in Sponsor 1 Study B, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
a	June 17, 2014	\$100.00	M.E.	DEMMING	Day 1
b	June 17, 2014	\$100.00	M.E.	DEMMING	Day 2
c	June 17, 2014	\$100.00	M.E.	DEMMING	Day 3
d	June 17, 2014	\$100.00	M.E.	DEMMING	Day 4
e	June 17, 2014	\$100.00	M.E.	DEMMING	Day 5
f	June 30, 2014	\$100.00	M.E.	DEMMING	Day 15
g	June 30, 2014	\$100.00	M.E.	DEMMING	Day 22
h	August 4, 2014	\$100.00	Nichole Bockman	DEMMING	Day 1
i	August 4, 2014	\$100.00	Nichole Bockman	DEMMING	Day 2
j	August 4, 2014	\$100.00	Nichole Bockman	DEMMING	Day 3
k	August 7, 2014	\$100.00	Nichole Bockman	DEMMING	Day 4
l	August 7, 2014	\$100.00	Nichole Bockman	DEMMING	Day 5
m	August 7, 2014	\$100.00	Nichole Bockman	DEMMING	Day 15
n	August 7, 2014	\$100.00	Nichole Bockman	DEMMING	Day 22
o	December 10, 2014	\$100.00	DEBRA ADAMSON	DEMMING	Day 1
p	December 10, 2014	\$100.00	DEBRA ADAMSON	DEMMING	Day 2
q	December 10, 2014	\$100.00	DEBRA ADAMSON	DEMMING	Day 3

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
r	December 10, 2014	\$100.00	DEBRA ADAMSON	DEMMING	Day 4
s	December 11, 2014	\$100.00	DEBRA ADAMSON	DEMMING	Day 5
t	December 22, 2014	\$100.00	DEBRA ADAMSON	DEMMING	Day 15
u	December 30, 2014	\$100.00	DEBRA ADAMSON	DEMMING	Day 22

C. Payments to Company 1

53. On or about the dates listed below, DEMMING, DEBRA ADAMSON, ASHLEY ADAMSON and WILLIAM ADAMSON caused Sponsor 1 to pay Company 1, in the manner and the amounts listed below, for participation in Sponsor 1 Study B, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
a	February 14, 2014	\$7,649.10
b	July 14, 2014	\$2,625.50
c	September 8, 2014	\$8,818.40
d	November 7, 2014	\$8,882.40
e	November 7, 2014	\$2,329.60
f	December 19, 2014	\$29,344.80
g	February 11, 2015	\$17,085.60
h	February 11, 2015	\$19,545.60
i	February 11, 2015	\$26,245.20
j	February 16, 2015	\$18,085.20
k	March 23, 2015	\$23,035.20
l	March 23, 2015	\$18,621.60
m	March 23, 2015	\$24,088.80
n	March 23, 2015	\$29,893.20

III. Sponsor 2 Study

54. On or about April 2, 2014, DEMMING and PANUTO signed a CTA with Sponsor 2 in connection with Sponsor 2 Study.

55. On or about March 2, 2015, PANUTO signed FDA Form 1572 as the PI responsible for conducting Sponsor 2 Study at the Middleburg Heights Office.

A. Study Subjects

56. On or about December 10, 2014, T.D. (an employee of Company 1 at the Smyrna Office) was enrolled as Subject Number 032 in Sponsor 2 Study.

57. On or about December 10, 2014, DEMMING signed an informed consent form certifying that she obtained informed consent from T.D. to participate in Sponsor 2 Study.

58. On or about December 23, 2014, V.J.F. (a real person known to the Grand Jury) was enrolled as Subject Number 039 in Sponsor 2 Study, using the correct date of birth and address for V.J.F., without the knowledge and consent of V.J.F.

59. On or about December 23, 2014, S.H. (an employee of Company 1 at the Middleburg Heights Office) signed an informed consent form certifying that S.H. obtained informed consent from V.J.F. to participate in Sponsor 2 Study.

60. On or about December 23, 2014, S.H. and PANUTO signed a Progress Note, which purported to reflect a patient encounter with V.J.F. and stated, in part: "Patient VJF was screened on 12/23/14. Patient read and consent to ICF. All questions were answered by study staff prior to signing ICF. A copy of ICF was given to patient. Pre-spirometry was performed. . . Blood work and urine collection were obtained. Dr. Panuto performed physical exam. . . . Post-spirometry was conducted and ECG was performed."

61. On or about November 21, 2014, S.E.K. (a real person known to the Grand Jury) was enrolled as Subject Number 025 in Sponsor 2 Study using the correct address and date of birth of S.E.K. but the former last name of S.E.K., without the knowledge and consent of S.E.K.

62. On or about November 21, 2014, DEMMING signed an informed consent form certifying that she obtained informed consent from S.E.K. to participate in Sponsor 2 Study.

63. On or about November 21, 2014, DEMMING and PANUTO signed a Progress Note, which purported to reflect a patient encounter with S.E.K. and stated, in part: "Patient was screened on 11/21/14. IC/EX criteria was reviewed. PE completed by Dr. Panuto. Vitals, hx, & labs were collected. Spirometry was completed. . . . ECG was completed."

64. On or about December 31, 2014, GWIN signed an informed consent form certifying that he obtained informed consent from S.E.K. to participate in Sponsor 2 Study.

B. ClinCard Payments

65. On or about the dates listed below, DEMMING, PANUTO and GWIN caused Company 1 to issue ClinCards in the names and for the amounts listed below, as payment for participation in Sponsor 2 study, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
a	December 23, 2014	\$80.00	V.J.F.	DEMMING	Screening
b	January 6, 2015	\$190.00	V.J.F.	DEMMING	Day 1
c	January 19, 2015	\$25.00	V.J.F.	DEMMING	Mid-Dosing PC
d	February 4, 2015	\$80.00	V.J.F.	DEMMING	Last Day
e	February 9, 2015	\$25.00	V.J.F.	DEMMING	Follow Up PC
f	December 10, 2014	\$80.00	T.D.	DEMMING	Screening
g	December 26, 2014	\$190.00	T.D.	DEMMING	Day 1
h	January 8, 2015	\$25.00	T.D.	DEMMING	Mid-Dosing PC
i	January 26, 2015	\$80.00	T.D.	DEMMING	Last Day
j	January 30, 2015	\$25.00	T.D.	DEMMING	Follow Up PC
k	November 21, 2014	\$80.00	S.E.K.	DEMMING	Screening
l	December 5, 2014	\$190.00	S.E.K.	DEMMING	Day 1
m	December 18, 2014	\$25.00	S.E.K.	DEMMING	Mid-Dosing PC
n	December 31, 2014	\$20.00	S.E.K.	DEMMING	Reconsent
o	December 31, 2014	\$80.00	S.E.K.	DEMMING	Last Day
p	January 1, 2015	\$25.00	S.E.K.	DEMMING	Follow Up PC

C. Payments to Company 1

66. On or about the dates listed below, DEMMING, PANUTO and GWIN caused Sponsor 2 to pay Company 1, in the manner and the amounts listed below, for participation in Sponsor 2 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
a	December 3, 2014	\$36,204.00
b	December 29, 2014	\$63,359.00
c	February 12, 2015	\$85,503.00
d	March 16, 2015	\$135,494.00
e	March 31, 2015	\$74,010.00
f	April 27, 2015	\$34,916.00
g	May 27, 2015	\$38,498.00
h	July 1, 2015	\$4,720.00

D. Payments to PANUTO

67. On or about the dates listed below, PANUTO invoiced Company 1 in the amounts listed below for PANUTO's involvement in Sponsor 2 Study, each invoice constituting a separate act in furtherance:

	Approx. Date of Invoice	Approx. Amount
a	April 2014	\$1,300.00
b	September 2014	\$2,100.00
c	October 2014	\$2,400.00
d	November 2014	\$2,550.00
e	December 2014	\$4,350.00
f	January 2015	\$3,750.00
g	February 2015	\$1,950.00
h	March 2015	\$1,650.00
i	April 2015	\$1,650.00

IV. **Sponsor 3 Study**

68. On or about August 19, 2014, DEMMING signed a Task Order Agreement with Sponsor 3 in connection with Sponsor 3 Study.

69. On or about May 20, 2015, PANUTO signed FDA Form 1572 as the PI responsible for conducting Sponsor 3 Study at the Middleburg Heights Office.

A. Study Subjects – Franklin Office

70. On or about December 30, 2014, “Ashley N. Bockman” was enrolled as Subject Number 160531g in Sponsor 3 Study using the correct date of birth, social security number, and address for ASHLEY ADAMSON.

71. On or about December 30, 2014, DEBRA ADAMSON signed an informed consent form certifying that she obtained informed consent from “Ashley N. Bockman” to participate in Sponsor 3 study.

72. On or about January 1, 2015, “Kathy C. Marley” was enrolled as Subject Number 160535k in Sponsor 3 Study using the correct date of birth, social security number, and address for M.E.

73. On or about January 1, 2015, DEBRA ADAMSON signed an informed consent form certifying that she obtained informed consent from “Kathy C. Marley” to participate in Sponsor 3 Study.

74. On or about January 4, 2016, WILLIAM ADAMSON sent an email to S.R. (an employee of Company 1), with a carbon copy to DEMMING, attaching a spreadsheet entitled “Franklin Tracker,” which contained visit and payment information for “Kathy C. Marley” for the Sponsor 3 Study.

B. Study Subjects – Middleburg Heights Office

75. On or about January 1, 2015, “Brian Sanders” was enrolled as Subject Number 164501f in Sponsor 3 Study.

76. On or about February 23, 2015, "Annie Daulson" was enrolled as Subject Number 164503b in Sponsor 3 Study using the correct date of birth and social security number for DEMMING.

77. On or about February 23, 2015, GWIN signed an informed consent form certifying that he obtained informed consent from "Annie Daulson" to participate in Sponsor 3 Study.

78. On or about February 23, 2015, GWIN and PANUTO signed a Progress Note, which purported to reflect a patient encounter with "Annie Daulson" and stated, in part: "Subject AED was screened on 2/23/15. Subject was given the informed consent to read. Subject was allowed time to read and ask questions of the study staff and PI before signing the informed concent [sic]. Subject was consented by Dan Gwin. . . . PI completed the CPE."

79. On or about February 25, 2015, PANUTO signed a document that purported to depict "Annie Daulson's" laboratory results, on which the typed patient name was blacked out to show only the initials A.D.

80. On or about May 3, 2015, "Susan Hennie" was enrolled as Subject Number 164505j in Sponsor 3 Study using the correct date of birth for S.H.

81. On or about May 3, 2015, DEMMING signed an informed consent form certifying that she obtained informed consent from "Susan Hennie" to participate in Sponsor 3 Study.

82. On or about May 3, 2015, PANUTO signed a document that purported to depict "Susan Hennie's" laboratory results, on which the typed patient name was blacked out to show only the initials S.H.

83. On or about February 10, 2016, "Andrew Z." was enrolled as Subject Number 164517d in Sponsor 3 Study using the correct date of birth and address for A.Z. (a real person known to the Grand Jury), without the knowledge and consent of A.Z.

84. On or about February 10, 2016, DEMMING signed an informed consent form certifying that she obtained informed consent from "Andrew Z." to participate in Sponsor 3 study.

85. On or about February 18, 2016, PANUTO signed a laboratory report, which purported to reflect urine and blood testing results collected from "Andrew Z."

86. On or about April 5, 2016, "Paul O'Neal" was enrolled as Subject Number 164533k in Sponsor 3 Study using a date of birth of November 11, 1981, and an address previously occupied by DEMMING.

87. On or about April 5, 2016, DEMMING signed an informed consent form certifying that she obtained informed consent from "Paul O'Neal" to participate in Sponsor 3 Study.

C. ClinCard Payments

88. On or about the dates listed below, DEMMING, PANUTO, DEBRA ADAMSON, ASHLEY ADAMSON, WILLIAM ADAMSON, GWIN, SMITH and O'MALLEY caused Company 1 to issue ClinCards, which DEMMING approved, in the names and for the amounts listed below, as payment for participation in Sponsor 3 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
a	December 30, 2014	\$175.00	ASHLEY ADAMSON	DEMMING	Day 0
b	January 5, 2015	\$175.00	ASHLEY ADAMSON	DEMMING	Day 3

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
c	January 6, 2015	\$175.00	ASHLEY ADAMSON	DEMMING	Day 7
d	January 27, 2015	\$175.00	ASHLEY ADAMSON	DEMMING	Day 28
e	January 1, 2015	\$175.00	M.E.	DEMMING	Day 0
f	January 4, 2015	\$175.00	M.E.	DEMMING	Day 3
g	January 8, 2015	\$175.00	M.E.	DEMMING	Day 7
h	January 29, 2015	\$175.00	M.E.	DEMMING	Day 28
i	January 3, 2015	\$175.00	SMITH	DEMMING	Day 0
j	January 4, 2015	\$175.00	SMITH	DEMMING	Day 3
k	January 8, 2015	\$175.00	SMITH	DEMMING	Day 7
l	January 29, 2015	\$175.00	SMITH	DEMMING	Day 28
m	February 10, 2015	\$50.00	SMITH	DEMMING	Manual Payment: \$50.00 for Nashville expenses
n	March 2, 2015	\$25.00	SMITH	DEMMING	Pregnancy Day 60
o	March 31, 2015	\$75.00	SMITH	DEMMING	Manual Payment: \$75.00 Reimbursment [sic] for [Sponsor 3] lab fees
p	May 4, 2015	\$175.00	S.H.	DEMMING	Day 0
q	May 6, 2015	\$175.00	S.H.	DEMMING	Day 3
r	May 12, 2015	\$175.00	S.H.	DEMMING	Day 7
s	May 28, 2015	\$175.00	S.H.	DEMMING	Day 28
t	June 8, 2015	\$67.00	S.H.	DEMMING	Manual Payment: \$67.00 2 labs draws for Southwest labs
u	June 8, 2015	\$22.85	S.H.	DEMMING	Manual Payment: \$22.85 third lab draw
v	February 10, 2016	\$175.00	Andrew Z.	DEMMING	Day 0
w	February 15, 2016	\$175.00	Andrew Z.	DEMMING	Day 3
x	February 18, 2016	\$175.00	Andrew Z.	DEMMING	Day 7
y	March 9, 2016	\$175.00	Andrew Z.	DEMMING	Day 28
z	April 5, 2016	\$175.00	Paul O'Neal	DEMMING	Day 0
aa	April 8, 2016	\$175.00	Paul O'Neal	DEMMING	Day 3
bb	April 11, 2016	\$175.00	Paul O'Neal	DEMMING	Day 7
cc	April 12, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 referraks [sic]
dd	April 14, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 Flu referral
ee	April 15, 2016	\$300.00	Paul O'Neal	DEMMING	Manual Payment: \$300.00 Office work

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
ff	April 18, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 Referral
gg	April 21, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 Ref
hh	April 22, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 Referral
ii	April 24, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 flu referral
jj	April 25, 2016	\$75.00	Paul O'Neal	DEMMING	Manual Payment: \$75.00 work done
kk	April 27, 2016	\$50.00	Paul O'Neal	DEMMING	Manual Payment: \$50.00 Work done 4/26-4/27
ll	April 28, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 referral
mm	April 29, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 work done 4/28-4/29
nn	May 2, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 work done 4/25
oo	May 3, 2016	\$175.00	Paul O'Neal	DEMMING	Day 28
pp	May 9, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 Work 5/4-5/6
qq	May 10, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 work 5/9-5/11
rr	May 13, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 Work done 5/11-5/13
ss	May 17, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 Work done
tt	May 19, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 Work done 5/17 and 5/18 5 hours today total
uu	May 25, 2016	\$120.00	Paul O'Neal	DEMMING	Manual Payment: \$120.00 Work done 5/23-5/24
vv	May 27, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 Work done
ww	May 31, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 Receipts
xx	June 1, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 work done

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
yy	June 6, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 receipts
zz	June 8, 2016	\$275.00	Paul O'Neal	DEMMING	Manual Payment: \$275.00 Work done
aaa	June 16, 2016	\$200.00	Paul O'Neal	DEMMING	Manual Payment: \$200.00 Referral Sponsor 5 and SAR
bbb	June 17, 2016	\$250.00	Paul O'Neal	DEMMING	Manual Payment: \$250.00 receipts
ccc	June 17, 2016	\$41.00	Paul O'Neal	DEMMING	Manual Payment: \$41.00 Receipts 2 hrs
ddd	June 30, 2016	\$350.00	Paul O'Neal	DEMMING	Manual Payment: \$300.00 Wirk [sic] done
eee	July 1, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 Work Done
fff	July 7, 2016	\$400.00	Paul O'Neal	DEMMING	Manual Payment: \$400.00 work done for July 1-10
ggg	July 7, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 referral [Sponsor] patient
hhh	July 12, 2016	\$200.00	Paul O'Neal	DEMMING	Manual Payment: \$200.00 receipts
iii	July 15, 2016	\$250.00	Paul O'Neal	DEMMING	Manual Payment: \$250.00 receipts and work done
jjj	July 21, 2016	\$250.00	Paul O'Neal	DEMMING	Manual Payment: \$250.00 receipts
kkk	July 24, 2016	\$175.00	Paul O'Neal	DEMMING	Manual Payment: \$175.00 Admin
lll	July 26, 2016	\$250.00	Paul O'Neal	DEMMING	Manual Payment: \$250.00 Admin
mmm	July 29, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 admin work done
nnn	July 31, 2016	\$250.00	Paul O'Neal	DEMMING	Manual Payment: \$250.00 work done
ooo	August 5, 2016	\$450.00	Paul O'Neal	DEMMING	Manual Payment: \$450.00 admin and moving help
ppp	August 12, 2016	\$300.00	Paul O'Neal	DEMMING	Manual Payment: \$300.00 Receipts

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
qqq	August 19, 2016	\$140.00	Paul O'Neal	DEMMING	Manual Payment: \$140.00 work done
rrr	August 22, 2016	\$25.00	Paul O'Neal	DEMMING	Pregnancy Day 60
sss	August 22, 2016	\$25.00	Paul O'Neal	DEMMING	Pregnancy Day 90
ttt	August 22, 2016	\$25.00	Paul O'Neal	DEMMING	Pregnancy Day 120
uuu	August 22, 2016	\$25.00	Paul O'Neal	DEMMING	Pregnancy Day 150
vvv	August 22, 2016	\$25.00	Paul O'Neal	DEMMING	Pregnancy D180
www	August 24, 2016	\$125.00	Paul O'Neal	DEMMING	Manual Payment: \$125.00 Work
xxx	August 29, 2016	\$200.00	Paul O'Neal	DEMMING	Manual Payment: \$200.00 receipts [sic]
yyy	August 31, 2016	\$125.00	Paul O'Neal	DEMMING	Manual Payment: \$125.00 admin
zzz	September 6, 2016	\$300.00	Paul O'Neal	DEMMING	Manual Payment: \$300.00 admin work
aaaa	September 13, 2016	\$350.00	Paul O'Neal	DEMMING	Manual Payment: \$350.00 Receipts

D. Payments to Company 1

89. On or about the dates listed below, DEMMING, PANUTO, DEBRA ADAMSON, ASHLEY ADAMSON, WILLIAM ADAMSON, GWIN, SMITH and O'MALLEY caused Sponsor 3 to pay Company 1, in the manner and the amounts listed below, for participation in Sponsor 3 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
Franklin Office		
a	January 20, 2015	\$26,000.00
b	February 26, 2015	\$173,500.00
c	February 26, 2015	\$27,750.00
d	March 12, 2015	\$327,510.00
e	April 9, 2015	\$129,355.00
f	May 7, 2015	\$107,680.00
g	June 11, 2015	\$5,385.00
h	August 7, 2015	\$17,245.00
i	September 3, 2015	\$130.00
j	October 8, 2015	\$25,315.00
k	November 6, 2015	\$1,565.00
l	February 18, 2016	\$6,075.00

	Approx. Date of Payment	Approx. Amount
m	February 18, 2016	\$60,380.00
n	March 17, 2016	\$33,065.00
o	March 17, 2016	\$27,565.00
p	May 12, 2016	\$98,760.00
q	June 9, 2016	\$128,380.00
r	July 6, 2016	\$11,380.00
s	August 18, 2016	\$4,585.00
Middleburg Heights Office		
t	March 12, 2015	\$25,000.00
u	April 9, 2015	\$315.00
v	May 7, 2015	\$13,065.00
w	June 11, 2015	\$12,815.00
x	July 30, 2015	\$37,815.00
y	August 7, 2015	\$880.00
z	September 3, 2015	\$26,130.00
aa	October 8, 2015	\$630.00
bb	November 6, 2015	\$630.00
cc	February 18, 2016	\$445.00
dd	February 18, 2016	\$30,500.00
ee	March 3, 2016	\$250.00
ff	March 17, 2016	\$33,000.00
gg	May 12, 2016	\$142,575.00
hh	June 9, 2016	\$139,085.00
ii	July 6, 2016	\$14,750.00
jj	August 18, 2016	\$4,840.00

E. Payments to PANUTO

90. On or about the dates listed below, PANUTO invoiced Company 1 in the amounts listed below for PANUTO's involvement in Sponsor 3 Study, each invoice constituting a separate act in furtherance:

	Approx. Date of Invoice	Approx. Amount
a	September 2014	\$1,750.00
b	January 2015	\$525.00
c	February 2015	\$175.00
d	March 2015	\$175.00
e	May 2015	\$525.00
f	June 2015	\$350.00
g	February 2016	\$175.00

	Approx. Date of Invoice	Approx. Amount
h	March 2016	\$875.00
i	April 2016	\$1,400.00

V. Sponsor 4 Study

91. On or about October 7, 2014, DEBRA ADAMSON signed a CTA with Sponsor 4 on behalf of Company 1 in connection with Sponsor 4 Study.

A. Study Subjects

92. On or about April 27, 2015, “Ashley Bockman,” which was the maiden name of ASHLEY ADAMSON, was enrolled as Subject Number 117 in Sponsor 4 Study using the correct date of birth for ASHLEY ADAMSON.

93. On or about April 27, 2015, DEBRA ADAMSON signed an informed consent form certifying that she obtained informed consent from “Ashley Bockman” to participate in Sponsor 4 Study.

94. On or about July 22, 2015, DEBRA ADAMSON signed a Progress Note, which purported to reflect a patient encounter with “Ashley Bockman” and stated, in part: “ANB’s blood was collected for repeat phosphorus per protocol. . . . She will be retested on 19 Aug 2015.”

95. On or about July 22, 2015, DEBRA ADAMSON created a laboratory report, which purported to reflect the results of a blood phosphorus test for “Ashley Bockman.”

96. On or about August 25, 2015, DEBRA ADAMSON created a laboratory report, which purported to reflect the results of a blood phosphorus test for “Ashley Bockman.”

97. On or about December 16, 2015, DEBRA ADAMSON signed a Drug Dispensing and Reconciliation [sic] Log certifying that she dispensed two dosages of the investigational drug to “Ashley Bockman.”

98. On or about April 27, 2015, "Hank Bobart" was enrolled as Subject Number 114 in Sponsor 4 Study using the correct date of birth and a previous address for WILLIAM ADAMSON.

99. On or about April 27, 2015, DEBRA ADAMSON signed an informed consent form certifying that she obtained informed consent from "Hank Bobart" to participate in Sponsor 4 Study.

100. On or about December 16, 2015, DEBRA ADAMSON signed a Drug Dispensing and Reconciliation [sic] Log certifying that she dispensed two dosages of the investigational drug to "Hank Bobart."

101. On or about February 1, 2016, WILLIAM ADAMSON sent an email to S.R., with a carbon copy to DEMMING, attaching a spreadsheet entitled "Franklin Tracker," which contained visit and payment information for "Hank Bobart" for the Sponsor 4 Study.

102. On or about May 6, 2015, "Jean T. Purvis" was screened for participation in Sponsor 4 Study using the correct date of birth and a previous address for T.D.

103. On or about May 6, 2015, DEBRA ADAMSON signed an informed consent form certifying that she obtained informed consent from "Jean T. Purvis" to participate in Sponsor 4 Study.

104. On or about May 27, 2015, "Jean T. Purvis" was enrolled as Subject Number 135 in Sponsor 4 Study using the correct date of birth and a previous address for T.D.

105. On or about May 27, 2015, DEBRA ADAMSON signed an informed consent form certifying that she obtained informed consent from "Jean T. Purvis" to participate in Sponsor 4 Study.

106. On or about December 16, 2015, DEBRA ADAMSON signed a Drug Dispensing and Reconciliation [sic] Log certifying that she dispensed two dosages of the investigational drug to “Jean T. Purvis.”

107. On or about June 1, 2015, “Amy Paulson,” the surname for whom was the maiden name of AMIE DEMMING, was screened for participation in Sponsor 4 Study.

108. On or about July 1, 2015, “Suzy A. Copeland,” the surname for whom was the maiden name of DEBRA ADAMSON, was screened for participation in Sponsor 4 Study.

B. ClinCard Payments

109. On or about the dates listed below, DEMMING, DEBRA ADAMSON, ASHLEY ADAMSON and WILLIAM ADAMSON caused Company 1 to issue ClinCards, which DEMMING approved, in the names and for the amounts listed below, as payment for participation in Sponsor 4 study, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
a	April 27, 2015	\$65.00	Ashley Bockman	DEMMING	Screening
b	May 6, 2015	\$65.00	Ashley Bockman	DEMMING	Day 0
c	May 12, 2015	\$65.00	Ashley Bockman	DEMMING	Day 5
d	May 18, 2015	\$65.00	Ashley Bockman	DEMMING	Day 14
e	June 3, 2015	\$65.00	Ashley Bockman	DEMMING	Day 28
f	June 17, 2015	\$65.00	Ashley Bockman	DEMMING	Day 42
g	July 22, 2015	\$25.00	Ashley Bockman	DEMMING	Manual Payment: \$25.00 Repeat lab phosphorus
h	August 25, 2015	\$25.00	Ashley Bockman	DEMMING	Manual Payment: \$25.00 Repeat phosphorus end of study
i	April 27, 2015	\$65.00	Hank Bobart	DEMMING	Screening

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
j	May 6, 2015	\$65.00	Hank Bobart	DEMMING	Day 0
k	May 12, 2015	\$65.00	Hank Bobart	DEMMING	Day 5
l	May 18, 2015	\$65.00	Hank Bobart	DEMMING	Day 14
m	June 3, 2015	\$65.00	Hank Bobart	DEMMING	Day 28
n	June 17, 2015	\$65.00	Hank Bobart	DEMMING	Day 42
o	July 22, 2015	\$200.00	Hank Bobart	DEMMING	Manual Payment: \$200.00 Bookshelves for office construction
p	August 4, 2015	\$100.00	Hank Bobart	DEMMING	Manual Payment: \$100.00 Referral for [Sponsor]
q	May 6, 2015	\$65.00	Jean T. Purvis	DEMMING	Screening
r	May 28, 2015	\$65.00	Jean T. Purvis	DEMMING	Day 0
s	May 28, 2015	\$65.00	Jean T. Purvis	DEMMING	Manual Payment: \$65.00 Patient originally screened under 8001-043. She has rescreened under 8001-065 for Sponsor 4 study which is allowed per protocol.
t	June 2, 2015	\$65.00	Jean T. Purvis	DEMMING	Day 5
u	June 10, 2015	\$65.00	Jean T. Purvis	DEMMING	Day 14
v	June 24, 2015	\$65.00	Jean T. Purvis	DEMMING	Day 28
w	July 8, 2015	\$65.00	Jean T. Purvis	DEMMING	Day 42
x	May 12, 2015	\$65.00	Amy Paulson	DEMMING	Screening
y	June 10, 2015	\$65.00	Amy Paulson	DEMMING	Manual Payment: \$65.00 rescreen new screening number is 8001-082
z	July 7, 2015	\$65.00	Suzy A. Copeland	DEMMING	Screening

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
aa	October 9, 2015	\$200.00	Suzy A. Copeland	DEMMING	Manual Payment: \$200.00 Referral for [Sponsor 3] study 2 pts

C. Payments to Company 1

110. On or about the dates listed below, DEMMING, DEBRA ADAMSON, ASHLEY ADAMSON and WILLIAM ADAMSON caused Sponsor 4 to pay Company 1, in the manner and the amounts listed below, for participation in Sponsor 4 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
a	August 4, 2015	\$92,647.50
b	September 14, 2015	\$119,382.50
c	October 26, 2015	\$131,567.50
d	February 1, 2016	\$136,696.25
e	October 20, 2016	\$5,952.50

VI. **Sponsor 5 Study**

111. On or about February 11, 2015, DEMMING and PANUTO signed a CTA with Sponsor 5 on behalf of Company 1 in connection with Sponsor 5 Study.

112. On or about October 7, 2015, PANUTO signed FDA Form 1572 as the PI responsible for conducting Sponsor 5 Study at the Middleburg Heights Office.

A. Study Subjects

113. On or about June 8, 2015, "Ashley Adams" was enrolled as Subject Number 026 in Sponsor 5 Study using the correct date of birth for ASHLEY ADAMSON.

114. On or about June 8, 2015, GWIN and PANUTO signed a Progress Note, which purported to reflect a patient encounter with "Ashley Adams" and stated, in part: "Subject A-A was screened on 6/8/15. Subject received the informed consent. Subject was allowed time to

read and ask questions of the PI and study staff before signing the informed consent. Subject was consented by Dan Gwin. . . . PI completed the CPE.”

115. On or about June 8, 2015, SMITH generated an Encounter Report dated March 9, 2015, and electronically signed by PANUTO on March 16, 2015, which purported to reflect a patient encounter with “Ashley Adams” but contained the correct date of birth for ASHLEY ADAMSON.

116. On or about June 12, 2015, GWIN signed an informed consent form certifying that he obtained informed consent from “Ashley Adams” to participate in Sponsor 5 Study.

117. On or about July 16, 2015, GWIN and PANUTO signed a Phone Call Note, which purported to reflect a patient encounter with “Ashley Adams.”

118. On or about August 20, 2015, R.C. (an employee of Company 1) conducted an internal audit for “Ashley Adams,” which affirmed, among other things, that: “[T]he subject was registered correctly”; “[T]here [is] sources documentation to support that all eligibility criteria were met”; “[T]he data quality [was] complete and appropriate”; and “[T]he case/medical history [was] maintained appropriately.”

119. On or about June 8, 2015, “Tammy Davis” was enrolled as Subject Number 027 in Sponsor 5 Study using the correct date of birth for T.D.

120. On or about June 8, 2015, GWIN signed an informed consent form certifying that he obtained informed consent from “Tammy Davis” to participate in Sponsor 5 Study.

121. On or about June 8, 2015, GWIN and PANUTO signed an informed consent form for “Tammy Davis,” which stated, in part: “The subject signed and dated the Informed Consent Form following a discussion of the study and prior to any study related procedures being performed. The risks and benefits of the study were explained.”

122. On or about June 8, 2015, GWIN and PANUTO signed a Progress Note, which purported to reflect a patient encounter with “Tammy Davis” and stated, in part: “Subject T-D was screened on 6/8/15. Subject received the informed consent to read. Subject was allowed time to read and ask questions of the study staff and PI before signing the informed consent. Subject was consented by D. Gwin. . . . PI completed the CPE. Pre and Post BD spiro was completed. ECG was obtained. . . . Blood samples were collected and shipped. Urine HCG was negative.”

123. On or about July 1, 2015, GWIN signed an informed consent form certifying that he obtained informed consent from “Tammy Davis” to participate in Sponsor 5 Study.

124. On or about July 29, 2015, GWIN and PANUTO shipped and caused to be shipped via FedEx blood and urine specimens for “Tammy Davis” to L.C., a third-party clinical laboratory and health care diagnostics company located in New Jersey, for laboratory analysis.

125. On or about August 5, 2015, GWIN and PANUTO signed a Phone Call Note, which purported to reflect a patient encounter with “Tammy Davis.”

126. On or about September 28, 2016, “Paul O’Neal” was enrolled as Subject Number 122 in Sponsor 5 Study using the correct date of birth for O’MALLEY.

127. On or about September 28, 2016, DEMMING signed an informed consent form certifying that she obtained informed consent from “Paul O’Neal” to participate in Sponsor 5 study.

B. ClinCard Payments

128. On or about the dates listed below, DEMMING, PANUTO, ASHLEY ADAMSON, GWIN and O’MALLEY caused Company 1 to issue ClinCards, which DEMMING

approved, in the names and for the amounts listed below, as payment for participation in Sponsor

5 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
a	June 8, 2015	\$60.00	Ashley Adams	DEMMING	Screening
b	June 12, 2015	\$70.00	Ashley Adams	DEMMING	Day 1
c	June 14, 2015	\$10.00	Ashley Adams	DEMMING	Day 2
d	June 14, 2015	\$60.00	Ashley Adams	DEMMING	Day 3
e	June 16, 2015	\$10.00	Ashley Adams	DEMMING	Day 4
f	June 16, 2015	\$60.00	Ashley Adams	DEMMING	Day 5
g	June 18, 2015	\$10.00	Ashley Adams	DEMMING	Day 6
h	June 18, 2015	\$70.00	Ashley Adams	DEMMING	Day 7
i	June 25, 2015	\$60.00	Ashley Adams	DEMMING	Day 8
j	June 25, 2015	\$70.00	Ashley Adams	DEMMING	Day 14
k	July 3, 2015	\$60.00	Ashley Adams	DEMMING	Day 21
l	July 15, 2015	\$60.00	Ashley Adams	DEMMING	Day 28
m	July 15, 2015	\$200.00	Ashley Adams	DEMMING	Manual Payment: \$200.00 referral 037 037 Sponsor 5
n	July 18, 2015	\$100.00	Ashley Adams	DEMMING	Manual Payment: \$100.00 Sponsor 5 referral
o	June 6, 2015	\$60.00	Tammy Davis	DEMMING	Screening
p	June 8, 2015	\$100.00	Tammy Davis	DEMMING	Manual Payment: \$100.00 referral for A-A Sponsor 5
q	July 1, 2015	\$70.00	Tammy Davis	DEMMING	Day 1
r	July 3, 2015	\$10.00	Tammy Davis	DEMMING	Day 2

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
s	July 3, 2015	\$60.00	Tammy Davis	DEMMING	Day 3
t	July 5, 2015	\$10.00	Tammy Davis	DEMMING	Day 4
u	July 5, 2015	\$60.00	Tammy Davis	DEMMING	Day 5
v	July 7, 2015	\$10.00	Tammy Davis	DEMMING	Day 6
w	July 7, 2015	\$70.00	Tammy Davis	DEMMING	Day 7
x	July 14, 2015	\$60.00	Tammy Davis	DEMMING	Day 8
y	July 14, 2015	\$70.00	Tammy Davis	DEMMING	Day 14
z	July 20, 2015	\$150.00	Tammy Davis	DEMMING	Manual Payment: \$150.00 referral for 1 Sponsor 5 screen and 1 sf for Sponsor 7
aa	July 22, 2015	\$60.00	Tammy Davis	DEMMING	Day 21
bb	July 29, 2015	\$60.00	Tammy Davis	DEMMING	Day 28
cc	September 28, 2016	\$60.00	Paul O'Neal	DEMMING	Manual Payment: \$60.00
dd	September 29, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 admin
ee	September 30, 2016	\$150.00	Paul O'Neal	DEMMING	Manual Payment: \$150.00 admin
ff	October 3, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 receipts
gg	October 3, 2016	\$250.00	Paul O'Neal	DEMMING	Manual Payment: \$250.00 admin
hh	October 7, 2016	\$100.00	Paul O'Neal	DEMMING	Manual Payment: \$100.00 admin
ii	October 13, 2016	\$250.00	Paul O'Neal	DEMMING	Manual Payment: \$250.00 receipts

C. Payments to Company 1

129. On or about the dates listed below, DEMMING, PANUTO, ASHLEY ADAMSON, GWIN and O'MALLEY caused Sponsor 5 to pay Company 1, in the manner and

amounts listed below, for participation in Sponsor 5 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
a	April 16, 2015	\$13,455.00
b	September 21, 2015	\$67,455.00
c	November 5, 2015	\$60,722.00
d	December 7, 2015	\$46,674.00
e	December 11, 2015	\$3,500.00
f	February 3, 2016	\$82,850.00
g	February 8, 2016	\$5,000.00
h	March 7, 2016	\$74,965.00
i	April 11, 2016	\$54,141.30
j	August 19, 2016	\$15,889.77
k	October 6, 2016	\$21,825.00
l	March 21, 2017	\$172,471.90

D. Payments to PANUTO

130. On or about the dates listed below, PANUTO invoiced Company 1 in the amounts listed below for PANUTO's involvement in the Sponsor 5 Study, each invoice constituting a separate act in furtherance:

	Approx. Date of Invoice	Approx. Amount
a	February 2015	\$1,750.00
b	March 2015	\$1,950.00
c	April 2015	\$1,950.00
d	May 2015	\$1,350.00
e	June 2015	\$1,350.00
f	July 2015	\$2,250.00
g	August 2015	\$1,650.00
h	September 2015	\$1,950.00
i	October 2015	\$750.00
j	November 2015	\$900.00
k	February 2016	\$450.00
l	March 2016	\$450.00
m	April 2016	\$300.00
n	May 2016	\$450.00
o	June 2016	\$450.00
p	July 2016	\$150.00

	Approx. Date of Invoice	Approx. Amount
q	August 2016	\$450.00
r	September 2016	\$450.00

E. Other Communications

131. On or about February 2, 2018, PANUTO sent an email to T.R. (an employee of Company 1) with the subject line “Sponsor 5,” in which he stated, in part: “[T]o the best of my knowledge, all of the subjects enrolled in [Sponsor 5] study are valid with self reported histories of asthma.”

VII. Sponsor 6 Study

132. On or about March 18, 2015, PANUTO signed FDA Form 1572 as the PI responsible for conducting Sponsor 6 Study at the Middleburg Heights Office.

133. On or about March 26, 2015, PANUTO signed FDA Form 1572 as the PI responsible for conducting Sponsor 6 Study at the Middleburg Heights Office.

134. On or about June 8, 2015, DEMMING and PANUTO signed a CTA with Sponsor 6 on behalf of Company 1 in connection with Sponsor 6 Study.

135. On or about May 18, 2016, PANUTO signed FDA Form 1572 as the PI responsible for conducting Sponsor 6 Study at the Middleburg Heights Office.

A. Study Subjects

136. On or about November 4, 2015, V.J.F. was enrolled as Subject Number 106 in Sponsor 6 Study, using the correct name and address for V.J.F. but a fictitious date of birth for V.J.F., without the knowledge and consent of V.J.F.

137. On or about November 4, 2015, DEMMING signed an informed consent form certifying that she obtained informed consent from V.J.F. to participate in Sponsor 6 Study.

138. On or about December 7, 2015, GWIN generated a Spirometry Report, which purported to depict the results of a spirometry test measuring lung function, for V.J.F.

139. On or about December 15, 2015, DEMMING forwarded to GWIN an email from B.S., a third-party company providing clinical trial support services, attaching a Spirometry Report for V.J.F.

140. On or about December 24, 2015, DEMMING forwarded to GWIN an email from B.S. attaching an Electrocardiogram ("ECG") Report, which purported to depict the results of an ECG test measuring the electrical activity of the heart, for V.J.F.

141. On or about August 18, 2016, GWIN and PANUTO signed a Progress Note, which purported to reflect a patient encounter with V.J.F. and stated, in part: "Subject VJF returned for Visit 14. The subject hasn't been compliant with home dosing. The subject forgot their diary. Vitals were obtained after resting for 5 minutes. ECG was obtained. . . . Pre and post spiro was completed. Safety labs were obtained and shipped. The subject will return on 8/19/16 for diary and dosing."

142. On or about August 19, 2016, GWIN created a Dosing Record stating that product kit numbers 4627336 and 8097603, which contained the investigational drug, were dispensed to V.J.F. at the Middleburg Heights Office.

143. On or about October 27, 2016, after B.B., the Senior Medical Director for Sponsor 6, confronted GWIN about a study monitor from Sponsor 6 locating product kit numbers 4627336 and 8097603 unopened and in the refrigerator at the Middleburg Heights Office, GWIN sent an email to B.B. in which he attached a photograph depicting the opened box for product kit number 4627336.

B. Shipments of Investigational Product

144. On or about the dates listed below, DEMMING, PANUTO and GWIN caused Sponsor 6 to send via FedEx the following shipments of investigational product to Company 1's Middleburg Heights Office for use in the Sponsor 6 Study, each shipment constituting a separate act in furtherance:

	Approx. Date of Shipment	Description of Shipment
a	September 14, 2015	Shipment No. 160095
b	October 19, 2015	Shipment No. 160141
c	November 19, 2015	Shipment No. 160176
d	December 14, 2015	Shipment No. 160209
e	December 17, 2015	Shipment No. 160234
f	January 7, 2016	Shipment No. 160311
g	February 3, 2016	Shipment No. 160347
h	February 10, 2016	Shipment No. 160363
i	March 10, 2016	Shipment No. 160421
j	April 18, 2016	Shipment No. 160492
k	April 26, 2016	Shipment No. 160608
l	May 16, 2016	Shipment No. 160669
m	July 5, 2016	Shipment No. 160806
n	July 6, 2016	Shipment No. 160855
o	August 24, 2016	Shipment No. 161006
p	October 31, 2016	Shipment No. 161098

C. ClinCard Payments

145. On or about the dates listed below, DEMMING, PANUTO and GWIN caused Company 1 to issue ClinCards, which DEMMING approved, in the names and for the amounts listed below, as payment for participation in Sponsor 6 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
a	November 4, 2015	\$75.00	V.J.F.	DEMMING	Screening
b	December 8, 2015	\$75.00	V.J.F.	DEMMING	Visit 2 Randomization
c	December 22, 2015	\$75.00	V.J.F.	DEMMING	Visit 3/Week 2
d	January 4, 2016	\$75.00	V.J.F.	DEMMING	Visit 4/Week 4
e	January 18, 2016	\$75.00	V.J.F.	DEMMING	Visit 5/Week 6

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
f	February 2, 2016	\$75.00	V.J.F.	DEMMING	Visit 6/Week 8
g	February 18, 2016	\$75.00	V.J.F.	DEMMING	Visit 7/Week 10
h	March 2, 2016	\$75.00	V.J.F.	DEMMING	Visit 8
i	March 16, 2016	\$75.00	V.J.F.	DEMMING	Visit 9
j	March 30, 2016	\$75.00	V.J.F.	DEMMING	Visit 10
k	April 13, 2016	\$75.00	V.J.F.	DEMMING	Visit 11
l	April 27, 2016	\$75.00	V.J.F.	DEMMING	Visit 12
m	May 12, 2016	\$75.00	V.J.F.	DEMMING	Visit 13
n	May 27, 2016	\$75.00	V.J.F.	DEMMING	Visit 14
o	June 9, 2016	\$75.00	V.J.F.	DEMMING	Visit 15
p	June 24, 2016	\$75.00	V.J.F.	DEMMING	Visit 16
q	July 14, 2016	\$75.00	V.J.F.	DEMMING	Visit 17
r	July 21, 2016	\$75.00	V.J.F.	DEMMING	Visit 18
s	August 5, 2016	\$75.00	V.J.F.	DEMMING	Visit 19
t	August 19, 2016	\$75.00	V.J.F.	DEMMING	Visit 20
u	September 1, 2016	\$75.00	V.J.F.	DEMMING	Visit 21
v	September 19, 2016	\$75.00	V.J.F.	DEMMING	Visit 22

D. Payments to Company 1

146. On or about the dates listed below, DEMMING, PANUTO and GWIN caused Sponsor 6 to pay Company 1, in the manner and amounts listed below, for participation in Sponsor 6 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
a	December 14, 2015	\$10,875.00
b	February 8, 2016	\$30,725.00
c	March 4, 2016	\$8,600.00
d	June 3, 2016	\$975.00
e	June 3, 2016	\$2,805.00
f	September 20, 2016	\$33,975.00
g	November 30, 2016	\$5,140.00
h	December 20, 2016	\$21,075.00

E. Payments to PANUTO

147. On or about the dates listed below, PANUTO invoiced Company 1 in the amounts listed below for PANUTO's involvement in Sponsor 6 Study, each invoice constituting a separate act in furtherance:

	Approx. Date	Approx. Amount
a	June 2015	\$1,250.00
b	October 2015	\$150.00
c	November 2015	\$300.00
d	April 2016	\$300.00
e	May 2016	\$150.00
f	June 2016	\$150.00

VIII. Sponsor 7 Study

148. On or about June 17, 2015, DEMMING and PANUTO signed a CTA with Sponsor 7 on behalf of Company 1 related to Sponsor 7 Study.

149. On or about May 13, 2015, PANUTO signed FDA Form 1572 as the PI responsible for conducting Sponsor 7 Study at the Middleburg Heights Office.

A. Study Subjects – Smyrna Office

150. On or about July 14, 2015, "Ashley Bockman," which was the maiden name of ASHLEY ADAMSON, was enrolled as Subject Number 2443 in Sponsor 7 Study using the correct date of birth and social security number for ASHLEY ADAMSON.

151. On or about July 14, 2015, T.D. signed an informed consent form certifying that she obtained informed consent from "Ashley Bockman" to participate in Sponsor 7 Study.

B. Study Subjects – Middleburg Heights Office

152. On or about July 23, 2015, "Ashley Adams" was enrolled as Subject Number 2612 in Sponsor 7 Study using a date of birth of February 13, 1985.

153. On or about July 23, 2015, GWIN signed an informed consent form certifying that he obtained informed consent from “Ashley Adams” to participate in Sponsor 7 Study.

154. On or about July 23, 2015, V.J.F. was enrolled as Subject Number 2615 in Sponsor 7 Study, using the correct name for V.J.F. but a fictitious date of birth for V.J.F., without the knowledge and consent of V.J.F.

155. On or about July 23, 2015, DEMMING signed an informed consent form certifying that she obtained informed consent from V.J.F. to participate in Sponsor 7 Study.

156. On or about July 23, 2015, GWIN created a Progress Note, which purported to reflect a patient encounter with V.J.F. and stated, in part: “Subject V.J.F. was screened on 7/23/15. Subject was issued the informed consent to read. Subject was allowed time to read and ask the PI and study staff questions before signing the informed consent. Subject was consented by A. Demming. . . . Pre BD spiro was completed. Blood samples were sent to the local lab. . . . PI completed the cpe [physical examination]. Subject completed the Post BD spiro. Subject meet[s] inclusion criteria.”

157. On or about July 23, 2015, SMITH generated an Encounter Report dated January 15, 2015, and electronically signed by PANUTO on January 16, 2015, which purported to reflect a patient encounter with V.J.F. but contained a fictitious date of birth for V.J.F.

158. On or about July 29, 2015, S.E.K. was enrolled as Subject Number 2712 in Sponsor 7 Study, using the correct address, date of birth and social security number of S.E.K. but the former last name of S.E.K., without the knowledge and consent of S.E.K.

159. On or about July 29, 2015, DEMMING signed an informed consent form certifying that she obtained informed consent from S.E.K. to participate in Sponsor 7 Study.

160. On or about July 29, 2015, DEMMING and GWIN created a Progress Note, which purported to reflect a patient encounter with S.E.K. and stated, in part: "Subject S.E.W. was screened on 7/29/15. Subject received the informed consent to read. Subject was allowed time to read and ask questions of the study staff and PI before signing the informed consent. Subject was consented by A. Demming. . . . Vitals were obtained after the subject was resting for 5 min. . . . Pre and Post BD spiro was completed. Subject took the 360 mg of Albuterol PI completed the CPE [physical exam]. Safety labs were sent to the lab. Subject received the . . . medication and was trained on diary and dosing."

161. On or about August 9, 2015, GWIN and PANUTO signed a Pulmonary Function Report, which purported to depict the results of a spirometry test measuring S.E.K.'s lung function.

C. Shipments of Investigational Product

162. On or about the dates listed below, DEMMING, PANUTO, ASHLEY ADAMSON, GWIN and SMITH caused Sponsor 7 to send via FedEx the following shipments of investigational product to Company 1's Middleburg Heights Office for use in the Sponsor 7 Study, each shipment constituting a separate act in furtherance:

	Approx. Date of Shipment	Description of Shipment
a	August 25, 2015	Order No. 605008
b	August 31, 2015	Order No. 606109
c	September 3, 2015	Order No. 606769
d	September 15, 2015	Order No. 608385

D. ClinCard Payments

163. On or about the dates listed below, DEMMING, PANUTO, ASHLEY ADAMSON, GWIN and SMITH caused Company 1 to issue ClinCards, which DEMMING

approved, in the names and for the amounts listed below, as payment for participation in Sponsor

7 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
a	July 23, 2015	\$125.00	V.J.F.	DEMMING	Screening
b	August 3, 2015	\$125.00	V.J.F.	DEMMING	Visit 2
c	August 4, 2015	\$500.00	V.J.F.	DEMMING	Visit 3 (Randomization)
d	August 17, 2015	\$125.00	V.J.F.	DEMMING	Visit 4
e	August 30, 2015	\$125.00	V.J.F.	DEMMING	Visit 5
f	August 31, 2015	\$125.00	V.J.F.	DEMMING	Visit 6
g	July 29, 2015	\$125.00	S.E.K.	DEMMING	Screening
h	August 9, 2015	\$125.00	S.E.K.	DEMMING	Visit 2
i	August 10, 2015	\$500.00	S.E.K.	DEMMING	Visit 3 (Randomization)
j	August 24, 2015	\$125.00	S.E.K.	DEMMING	Visit 4
k	September 3, 2015	\$125.00	S.E.K.	DEMMING	Visit 5
l	September 8, 2015	\$125.00	S.E.K.	DEMMING	Visit 6
m	July 15, 2015	\$125.00	Ashley Bockman	DEMMING	Screening
n	July 27, 2015	\$125.00	Ashley Bockman	DEMMING	Visit 2
o	July 28, 2015	\$500.00	Ashley Bockman	DEMMING	Visit 3 (Randomization)
p	August 4, 2015	\$100.00	Ashley Bockman	DEMMING	Manual Payment: \$100.00 manual payment for subject 10176-2485
q	August 4, 2015	\$100.00	Ashley Bockman	DEMMING	Manual Payment: \$100.00 manual payment for subject 10176-2441
r	August 12, 2015	\$125.00	Ashley Bockman	DEMMING	Visit 4
s	August 26, 2015	\$125.00	Ashley Bockman	DEMMING	Visit 5
t	August 27, 2015	\$125.00	Ashley Bockman	DEMMING	Visit 6
u	July 23, 2015	\$125.00	Ashley Adams	DEMMING	Screening
v	July 24, 2015	\$100.00	Ashley Adams	DEMMING	Manual Payment: \$100.00 referral for V.J.F. #6215 for Sponsor 7
w	July 28, 2015	\$75.00	Ashley Adams	DEMMING	Manual Payment: \$75.00 sf referral
x	July 30, 2015	\$200.00	Ashley Adams	DEMMING	Manual Payment: \$200.00 referrak [sic] for

	Approx. Date of Issuance	Approx. Amount	Name on ClinCard	Approved By	Description of Payment
					DTF 92699) and PYM (2719) for screens Sponsor 7 7/29 & 7/30
y	August 3, 2015	\$125.00	Ashley Adams	DEMMING	Visit 2
z	August 4, 2015	\$500.00	Ashley Adams	DEMMING	Visit 3 (Randomization)
aa	August 7, 2015	\$100.00	Ashley Adams	DEMMING	Manual Payment: \$100.00 referral for TMT Sponsor 7
bb	August 17, 2015	\$125.00	Ashley Adams	DEMMING	Visit 4
cc	August 26, 2015	\$100.00	Ashley Adams	DEMMING	Manual Payment: \$100.00 cbh referral Sponsor 7
dd	August 30, 2015	\$125.00	Ashley Adams	DEMMING	Visit 5
ee	August 31, 2015	\$125.00	Ashley Adams	DEMMING	Visit 6
ff	September 2, 2015	\$100.00	Ashley Adams	DEMMING	Manual Payment: \$100.00 referral for 3361 Sponsor 7

E. Payments to Company 1

164. On or about the dates listed below, DEMMING, PANUTO, ASHLEY ADAMSON, GWIN and SMITH caused Sponsor 7 to pay Company 1, in the manner and amounts listed below, for participation in Sponsor 7 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
Smyrna Office		
a	November 9, 2015	\$343,674.00
b	November 23, 2015	\$7,695.00
c	December 7, 2015	\$55,647.00
Middleburg Heights Office		
d	August 13, 2015	\$8,127.00
e	September 16, 2015	\$90,589.50
f	October 21, 2015	\$362,659.50
g	November 23, 2015	\$14,445.00

	Approx. Date of Payment	Approx. Amount
h	November 23, 2015	\$79,546.50
i	January 25, 2016	\$11,983.50

F. Payments to PANUTO

165. On or about the dates listed below, PANUTO invoiced Company 1 in the amounts listed below for PANUTO's involvement in Sponsor 7 Study, each invoice constituting a separate act in furtherance:

	Approx. Date	Approx. Amount
a	June 2015	\$2,250.00
b	July 2015	\$1,200.00
c	August 2015	\$3,600.00
d	September 2015	\$400.00

IX. Sponsor 8 Study

166. On or about November 12, 2015, DEMMING and PANUTO signed a CTA with Sponsor 8 in connection with Sponsor 8 Study.

167. On or about November 19, 2015, PANUTO signed FDA Form 1572 as the PI responsible for conducting Sponsor 8 Study at the Middleburg Heights Office.

A. Study Subjects

168. On or about February 2, 2016, T.D. was enrolled as Subject Number 004667 in Sponsor 8 Study using a false date of birth and social security number.

169. On or about February 2, 2016, GWIN signed an informed consent form certifying that he obtained informed consent from T.D. to participate in Sponsor 8 Study.

170. On or about February 2, 2016, GWIN and PANUTO signed a Pulmonary Function Report, which purported to depict the results of a spirometry test measuring T.D.'s lung function.

B. Shipments of Investigational Product

171. On or about the dates listed below, DEMMING, PANUTO and GWIN caused Sponsor 8 to send via UPS the following shipments of investigational product to Company 1's Middleburg Heights Office for use in the Sponsor 8 Study, each shipment constituting a separate act in furtherance:

	Approx. Date of Shipment	Description of Shipment
a	January 4, 2016	Order No. RTP2637166
b	January 26, 2016	Order No. RTP2659527
c	February 4, 2016	Order No. RTP2668529
d	February 16, 2016	Order No. RTP2675398
e	February 16, 2016	Order No. RTP2675837
f	February 17, 2016	Order No. RTP2676064
g	February 23, 2016	Order No. RTP2681011
h	March 1, 2016	Order No. RTP2685471
i	March 1, 2016	Order No. RTP2685692
j	March 2, 2016	Order No. RTP2686155
k	March 3, 2016	Order No. RTP2686299
l	March 7, 2016	Order No. RTP2686662
m	March 21, 2016	Order No. RTP2688236
n	March 28, 2016	Order No. RTP2689026
o	April 4, 2016	Order No. RTP2689839
p	April 19, 2016	Order No. RTP2691540
q	April 20, 2016	Order No. RTP2691733
r	April 21, 2016	Order No. RTP2692064
s	April 25, 2016	Order No. RTP2693304
t	April 25, 2016	Order No. RTP2695244
u	May 9, 2016	Order No. RTP2706320
v	May 16, 2016	Order No. RTP2710620
w	May 20, 2016	Order No. RTP2714741
x	June 6, 2016	Order No. RTP2724961
y	June 10, 2016	Order No. RTP2729290
z	June 23, 2016	Order No. RTP2737468
aa	July 5, 2016	Order No. RTP2743948
bb	July 16, 2016	Order No. RTP2752779
cc	July 16, 2016	Order No. RTP2752915
dd	August 19, 2016	Order No. RTP2774638
ee	August 19, 2016	Order No. RTP2775281
ff	August 23, 2016	Order No. RTP2775921

C. ClinCard Payments

172. On or about the dates listed below, DEMMING, PANUTO and GWIN caused Company 1 to issue ClinCards, which DEMMING approved, in the names and for the amounts listed below, as payment for participation in Sponsor 8 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Issuance	Approx. Amount	Issued To	Approved By	Description of Payment
a	February 5, 2016	\$100.00	Tammy Davis	DEMMING	Visit 1
b	February 8, 2016	\$100.00	Tammy Davis	DEMMING	Visit 2
c	March 8, 2016	\$100.00	Tammy Davis	DEMMING	Visit 3
d	April 5, 2016	\$100.00	Tammy Davis	DEMMING	Visit 4
e	May 4, 2016	\$100.00	Tammy Davis	DEMMING	Visit 5
f	July 23, 2016	\$100.00	Tammy Davis	DEMMING	Visit 6
g	August 17, 2016	\$100.00	Tammy Davis	DEMMING	Visit 7

D. Payments to Company 1

173. On or about the dates listed below, DEMMING, PANUTO and GWIN caused Sponsor 8 to pay Company 1, in the manner and amounts listed below, for participation in Sponsor 8 Study, each payment constituting a separate act in furtherance:

	Approx. Date of Payment	Approx. Amount
a	February 16, 2016	\$5,018.40
b	February 16, 2016	\$1,318.50
c	February 16, 2016	\$2,637.00
d	February 16, 2016	\$1,318.50
e	February 16, 2016	\$7,527.50
f	February 16, 2016	\$1,318.50
g	February 29, 2016	\$2,637.00
h	February 29, 2016	\$3,955.50
i	February 29, 2016	\$2,637.00
j	February 29, 2016	\$3,572.10
k	February 29, 2016	\$3,699.90
l	February 29, 2016	\$1,190.70
m	February 29, 2016	\$2,381.40
n	March 7, 2016	\$1,318.50
o	March 7, 2016	\$1,190.70

	Approx. Date of Payment	Approx. Amount
p	March 7, 2016	\$3,116.70
q	June 17, 2016	\$13,554.00
r	July 15, 2016	\$67,854.90
s	August 5, 2016	\$11,642.40
t	August 22, 2016	\$10,672.20
u	October 7, 2016	\$9,758.70
v	December 5, 2016	\$16,017.30

E. Payments to PANUTO

174. On or about the dates listed below, PANUTO invoiced Company 1 in the amounts listed below for PANUTO's involvement in Sponsor 8 Study, each invoice constituting a separate act in furtherance:

	Approx. Date	Approx. Amount
a	November 2015	\$1,500.00
b	March 2016	\$1,225.00
c	April 2016	\$350.00

All in violation of Title 18, United States Code, Section 1349.

COUNTS 2-8
(Mail Fraud, 18 U.S.C. §§ 1341 and 2)

The Grand Jury further charges:

175. The factual allegations contained in Paragraphs 1 through 174 are re-alleged and incorporated as though fully set forth herein.

176. From in or around January 2013 through in or around March 2018, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendants AMIE DEMMING, JOHN PANUTO, ASHLEY ADAMSON, DANIEL GWIN, BRENT SMITH and WALTER O'MALLEY devised and intended to devise a scheme and artifice to defraud the Sponsors and to obtain money from the Sponsors by materially false and fraudulent pretenses, representations, and promises.

177. On or about the following dates, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendants, having devised and intended to devise any scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations and promises, for the purpose of executing such scheme and artifice, placed, and caused to be placed, in any depository for mail matter, any matter and thing to be sent and delivered by the Postal Service, and took and received from the Postal Service, any such matter and thing delivered by the Postal Service, including the following mailings, each representing a separate count of this Indictment:

Count	Date	Description of Mailing	Method	Sender/ Location	Recipient/ Location	Defendants
2	7/29/2015	Shipment of blood and urine specimens for subject "Tammy Davis" in Sponsor 5 Study	FedEx	Company 1 Middleburg Heights, Ohio	L.C. Cranford, New Jersey	DEMMING / PANUTO / ASHLEY ADAMSON / GWIN / O'MALLEY
3	5/16/2016	Shipment No. 160669 of investigational product for use in Sponsor 6 Study	FedEx	Sponsor 6 Malvern, Pennsylvania	Company 1 Middleburg Heights, Ohio	DEMMING / PANUTO / GWIN
4	7/5/2016	Shipment No. 160806 of investigational product for use in Sponsor 6 Study	FedEx	Sponsor 6 Malvern, Pennsylvania	Company 1 Middleburg Heights, Ohio	DEMMING / PANUTO / GWIN
5	8/25/2015	Order No. 605008 of investigational product for use in Sponsor 7 Study	FedEx	Sponsor 7 Philadelphia, Pennsylvania	Company 1 Middleburg Heights, Ohio	DEMMING / PANUTO / ASHLEY ADAMSON / GWIN / SMITH
6	9/14/2015	Order No. 608385 of investigational product for use in Sponsor 7 Study	FedEx	Sponsor 7 Philadelphia, Pennsylvania	Company 1 Middleburg Heights, Ohio	DEMMING / PANUTO / ASHLEY ADAMSON / GWIN / SMITH
7	1/4/2016	Order No. RTP2637166 of investigational	UPS	Sponsor 8 Zebulon, North Carolina	Company 1 Middleburg Heights, Ohio	DEMMING / PANUTO / GWIN

Count	Date	Description of Mailing	Method	Sender/ Location	Recipient/ Location	Defendants
		product for use in Sponsor 8 Study				
8	3/28/2016	Order No. RTP2689026 of investigational product for use in Sponsor 8 Study	UPS	Sponsor 8 Zebulon, North Carolina	Company 1 Middleburg Heights, Ohio	DEMMING / PANUTO / GWIN

All in violation of Title 18, United States Code, Sections 1341 and 2.

COUNTS 9-10

(Wire Fraud, 18 U.S.C. §§ 1343 and 2)

The Grand Jury further charges:

178. The factual allegations contained in Paragraphs 1 through 174 are re-alleged and incorporated as though fully set forth herein.

179. From in or around January 2013 through in or around March 2018, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendants AMIE DEMMING, DEBRA ADAMSON, ASHLEY ADAMSON, and WILLIAM ADAMSON knowingly devised, and intended to devise, a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations, and promises.

180. On or about the dates listed below, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendants, for the purpose of executing and attempting to execute the foregoing scheme and artifice, transmitted and caused to be transmitted, writings, signs, signals, pictures, and sounds by means of wire and radio communication, in interstate commerce, to wit: email communications, as described below, each representing a separate count of this

Indictment:

Count	Date	Description of Wire	Origination/ Location	Transmittal Information	Destination/ Location	Defendants
9	1/4/16	Email to S.R., cc DEMMING, from WILLIAM ADAMSON about Sponsor 3 Study	WILLIAM ADAMSON via IP address in Tennessee	Transmitted via email server located in California or Virginia	DEMMING in Northern District of Ohio	DEMMING / DEBRA ADAMSON / ASHLEY ADAMSON / WILLIAM ADAMSON
10	2/1/16	Email to S.R., cc DEMMING, from WILLIAM ADAMSON about Sponsor 4 Study	WILLIAM ADAMSON via IP address in Tennessee	Transmitted via email server located in California or Virginia	DEMMING in Northern District of Ohio	DEMMING / DEBRA ADAMSON / ASHLEY ADAMSON / WILLIAM ADAMSON

All in violation of Title 18, United States Code, Sections 1343 and 2.

COUNTS 11-12

(Aggravated Identity Theft, 18 U.S.C. § 1028A(a)(1))

The Grand Jury further charges:

181. The factual allegations contained in Paragraphs 1 through 174 are re-alleged and incorporated as though fully set forth herein.

182. On or about the dates listed below, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendant AMIE DEMMING, during and in relation to felony violation(s) of Title 18, United States Code, Section 1341 (Mail Fraud), knowingly transferred, possessed and used without lawful authority a means of identification of the persons identified below (real persons known to the Grand Jury), knowing that the means of identification belonged to another person, to wit, DEMMING, without authorization, used the names, dates of birth, social security numbers and signatures of the persons identified below to enroll them as subjects in clinical trials, each use constituting a separate count:

Count	Date	Study/Subject Number	Identity
11	7/29/2015	Sponsor 7 Study/Subject Number 2712	S.E.K.
12	11/4/2015	Sponsor 6 Study/Subject Number 106	V.J.F.

All in violation of Title 18, United States Code, Section 1028A(a)(1).

COUNT 13

(Conspiracy to Defraud the United States, 18 U.S.C. § 371)

The Grand Jury further charges:

183. The factual allegations contained in Paragraphs 1 through 174 are re-alleged and incorporated as though fully set forth herein.

184. From in or around January 2013 though in or around March 2018, the exact dates being unknown to the Grand Jury, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendants AMIE DEMMING, JOHN PANUTO, DEBRA ADAMSON, ASHLEY NICHOLE ADAMSON, WILLIAM ADAMSON, DANIEL GWIN, BRENT SMITH and WALTER O'MALLEY did knowingly and intentionally combine, conspire, confederate and agree with each other, and with others both known and unknown to the Grand Jury:

a. to defraud the United States and an agency thereof, that is, to impede, impair, obstruct, and defeat the lawful and legitimate functions of the FDA to protect the health and safety of the public by ensuring that drugs intended for use in humans were safe and effective for their intended uses and that clinical investigations of human drugs were conducted ethically and to minimize patient harm; and

b. to commit an offense against the United States, that is, to knowingly and willfully make materially false, fictitious, and fraudulent statements and representations and falsify and conceal material facts in a matter within the jurisdiction of the FDA, an agency of the executive branch of the United States, in violation of Title 18, United States Code, Section 1001.

Objects of the Conspiracy

185. The objects of the conspiracy were to: (1) circumvent the FDA's oversight of clinical investigations; (2) use material misstatements and omissions to defraud the FDA; (3) prevent detection of the conspiracy by the FDA; and (4) enrich the conspirators and others.

Manner and Means

186. It was part of the conspiracy that:

- a. Defendants and their co-conspirators carried out the conspiracy through the manner and means alleged in Paragraph 34 above.
- b. Defendants and their co-conspirators caused the submission of false, fictitious and misleading documentation concerning the Sponsors' clinical investigations to the FDA.
- c. To lull the FDA, to impair and impede its lawful functions, including its function of overseeing clinical investigations, and to avoid FDA scrutiny of the Sponsors' studies, Defendants and their co-conspirators knowingly made false statements to an FDA investigator and concealed their knowledge of fictitious study subjects during the FDA Inspection.
- d. To lull the FDA, to impair and impede its lawful functions, including its function of overseeing clinical investigations, and to avoid FDA scrutiny of the Sponsors' studies, Defendants and their co-conspirators knowingly made false statements to the FDA and concealed their knowledge of fictitious study subjects in response to the FDA's observations concerning the FDA Inspection.

OVERT ACTS

187. In furtherance of the conspiracy and to achieve its objectives, one or more members of the conspiracy committed the following overt acts, among others, in the Northern District of Ohio, Eastern Division, and elsewhere:

188. The acts in furtherance set forth in Paragraphs 35 through 174 are incorporated by reference as if fully restated herein.

189. On or about October 20, 2017, PANUTO sent an email to T.R., who was present for the FDA Inspection, with the subject line "Sponsor 8 Study," in which PANUTO stated, in part: "I was provided descriptions, unique identifiers, occupations, and picture confirmations in regards to these patients from multiple sources confirming their existence and participation in studies."

190. On or about December 6, 2017, at the close of the FDA Inspection, PANUTO told an FDA investigator that all of the subjects in Sponsor 8 Study were real.

191. On or about December 20, 2017, following the FDA Inspection and in response to the FDA Form 483 observations, PANUTO sent a letter to the FDA in which he stated, in part, the following, each statement constituting a separate overt act:

a. In response to Observation 1: "The initial spirometry data [for Sponsor 8 Study Subject 004667] was signed off by myself, Dr. Panuto, on February 6, 2016 as an over read."

b. In response to Observation 2: "I acknowledge the observation that the investigational drug disposition records [for Sponsor 6 Study, Subject Number 106] were inaccurate. Please note that I was not present at the study site when the investigational drug product was dispensed to subject 106 on August 8, 2017 visit."

c. In response to Observation 3: "I acknowledge the FDA's observation that in both [Sponsor 6 Study and Sponsor 8 Study] protocols, there was a lapse in maintaining adequate case history with respect to observations and data pertinent to investigation. Any such documentation lapses were inadvertent."

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

COUNT 14

(Failure to Maintain Adequate Records,
21 U.S.C. §§ 331(e), 333(a)(2), and 355(i); 21 C.F.R. § 312.62(b))

The Grand Jury further charges:

192. The factual allegations contained in Paragraphs 1 through 191 are re-alleged and incorporated as though fully set forth herein.

193. From on or about March 2, 2015, through on or about December 20, 2017, in the Northern District of Ohio, Eastern Division, and elsewhere, Defendant JOHN PANUTO, with intent to defraud and mislead, failed to prepare and maintain records required under Title 21, United States Code, Section 355(i), and Title 21, Code of Federal Regulations, Section 312.62(b), to wit, adequate and accurate case histories on individuals administered an investigational drug or employed as a control in an investigation in which Defendant JOHN PANUTO was a Principal Investigator.

In violation of Title 21, United States Code, Sections 331(e), 333(a)(2), and 355(i); and Title 21, Code of Federal Regulations, Section 312.62(b).

FORFEITURE

The Grand Jury further alleges:

194. The allegations of Counts 1 through 10 and 13 are hereby realleged and incorporated herein by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 981(a)(1)(C); Title 28, United States Code, Section 2461(c). As a result of the foregoing offenses, Defendants AMIE DEMMING, JOHN PANUTO, DEBRA ADAMSON, ASHLEY NICHOLE ADAMSON, WILLIAM ADAMSON, DANIEL GWIN, BRENT SMITH, and WALTER O'MALLEY, shall forfeit to the United States all property, real and personal, which constitutes or is derived from proceeds they obtained directly or indirectly as a result of such violations; and all property, real and personal, which constitutes or is derived from gross proceeds traceable to the commission of such offenses.

A TRUE BILL.

Original document - Signatures on file with the Clerk of Courts, pursuant to the E-Government Act of 2002.