UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

21-20106-CR-SCOLA/GOODMAN

CASE NO. _____

18 U.S.C. § 1349
18 U.S.C. § 1341
18 U.S.C. § 1956(a)(1)(B)(i)
18 U.S.C. § 1957(a)
18 U.S.C. § 1001(a)(2)
18 U.S.C. § 2
18 U.S.C. § 981(a)(1)(C)
18 U.S.C. § 982

UNITED STATES OF AMERICA

vs.

MARTIN VALDES,
FIDALGIS FONT,
JULIO LOPEZ, and
DUNIEL TEJEDA,

Defendants.
_____/

INDICTMENT

The Grand Jury charges that:

GENERAL ALLEGATIONS

At various times relevant to this Indictment:

1. Clinical research trials, also known as clinical investigations, were research studies conducted on voluntary human subjects designed to answer specific questions about the safety or effectiveness of new drugs. Drug developers, or "sponsors," initiated and took responsibility for clinical research trials.

2. The United States Food and Drug Administration ("FDA") was responsible for ensuring that drugs intended for human use were safe and effective. The FDA relied on the

truthfulness and accuracy of the results of clinical research trials to make regulatory decisions about the approval of new drugs, with the ultimate goal of ensuring that all FDA-approved drugs were safe and effective for their approved uses in humans.

3. Before beginning a clinical research trial, sponsors were required to provide the FDA with extensive information regarding the proposed trial, including a detailed investigation plan known as a "study protocol." The study protocol described, among other things, the eligibility criteria for individuals to enroll as study subjects, schedules of tests and procedures, drug and dosage regimens, the length of the study, and the health outcomes to be measured by the study. Clinical research trials were required to be conducted according to the study protocol, as well as any applicable laws and FDA regulations.

4. Sponsors generally retained contract research organizations ("CROs") to oversee and conduct various aspects of clinical research trials. Sponsors and CROs typically contracted with multiple research sites to perform clinical research trials. Under such an arrangement, each individual research site was responsible for identifying study subjects, enrolling them into the study, performing the study, gathering data, and reporting the data to the sponsor and/or CRO, in accordance with the study protocol.

5. Each research site had a principal investigator, also known as a clinical investigator. The principal investigator was the individual responsible for conducting the clinical investigation at that site and ensuring that the clinical research trial was conducted according to the study protocol and in compliance with all applicable FDA regulations. Responsibilities of the principal investigator included personally conducting or supervising the study, including all requirements regarding the qualification of the subjects, the dispensation of study medication, and the collection and reporting of data; obtaining informed consent from study subjects; reporting adverse events

that occur during the study; and ensuring that all employees working on the study meet those same obligations. Sub-investigators worked under the direction of and assisted the principal investigator in conducting clinical trials.

6. Principal investigators were also required, by regulation, to prepare and maintain records relating to clinical research trials. These records, known as "case histories," included adequate records of the disposition of the study drug, including dates and quantities of drugs dispensed to subjects; informed consent forms and medical records for each subject participating in the clinical research trial; and records of all observations and other data pertinent to the investigation for each subject administered an experimental drug.

7. The FDA had the authority to inspect clinical investigators to ensure that investigators were complying with all applicable laws and regulations in conducting clinical trials. The FDA's inspection authority included the authority to review case histories and other records maintained by the clinical investigator.

8. Clinical investigators provided to the sponsor and/or CRO the information about each subject or enrollee in the study, including his or her medical history, laboratory results, and reaction to the drug under study. The sponsor then provided the information to the FDA for its use in evaluating whether the drug was safe and effective and should be approved for its intended use.

The Defendants and Their Co-Conspirators

9. Tellus Clinical Research, Inc. ("Tellus") was a medical clinic incorporated in Miami, Florida, that conducted clinical research trials of new drugs for pharmaceutical companies and other sponsors. Tellus's principal place of business was on Sunset Drive in Miami-Dade

County, Miami, Florida.

10. Defendant **MARTIN VALDES** resided in Coral Gables, Florida, and was a licensed medical doctor in the State of Florida. From in or around September 2013 and continuing through in or around May 2016, **VALDES** was the principal investigator responsible for conducting clinical research trials at Tellus.

11. Defendant **FIDALGIS FONT** resided in Miami, Florida. From in or around September 2012 and continuing through in or around September 2016, **FONT** was the chief executive officer of Tellus.

12. Defendant **JULIO LOPEZ** resided in Miami, Florida. From in or around April 2014 and continuing through in or around February 2016, **LOPEZ** was a study coordinator at Tellus.

13. Defendant **DUNIEL TEJEDA** resided in Miami, Florida. From in or around September 2013 and continuing through in or around May 2016, **TEJEDA** was a project manager and study coordinator at Tellus.

14. Person 1 was a clinical research coordinator at Tellus from in or around September 2013 and continuing through in or around May 2016.

15. Person 2 was a research assistant and assistant study coordinator at Tellus from in or around December 2014 and continuing through in or around June 2016.

16. Person 3 was a sub-investigator at Tellus from in or around April 2014 and continuing through in or around April 2016.

17. Person 4 was an assistant study coordinator at Tellus from in or around June 2014 and continuing through in or around July 2016.

CLINICAL TRIALS AT TELLUS

18. Between at least in or around February 2014 and at least in or around July 2016, Tellus, the Defendants, Person 1, Person 2, Person 3, and Person 4 conducted various clinical trials on behalf of sponsors and CROs located throughout the United States.

19. Among the clinical trials Tellus contracted to conduct were two trials concerning a new investigational drug intended to treat patients suffering from opioid dependency (collectively, "the opioid dependency trials"); two trials concerning a new investigational drug intended to treat patients suffering from irritable bowel syndrome (collectively, "the IBS trials"), and one trial concerning a new investigational drug intended to treat patients suffering from diabetic nephropathy, a kidney disease ("the diabetes trial").

20. Prior to beginning a clinical trial, Tellus and **MARTIN VALDES**, as principal investigator, entered into a "Clinical Trial Agreement" or similar contract with a sponsor or CRO. Clinical Trial Agreements require, among other things, that investigators follow the study protocol. At or around the same time Tellus entered a Clinical Trial Agreement, **VALDES**, as the principal investigator responsible for conducting the trial, also signed a Form FDA 1572, in which he agreed to comply with the terms of the study protocol and all applicable FDA regulations.

21. The study protocols required subjects to meet certain eligibility criteria to be enrolled in the study. For example, among other things, the opioid dependency trials required subjects to meet certain criteria for opioid dependence, the IBS trials required subjects to have been diagnosed with irritable bowel syndrome with diarrhea, and the diabetes trial required subjects to have documented diabetic nephropathy and have certain levels of a specific protein, albumin, in their urine.

22. The Clinical Trial Agreements between Tellus and its sponsors or CROs also at

times included a schedule of payments the sponsor would pay Tellus per study subject for each procedure, test, office visit, or other event required under the study protocol, in addition to other fees. The Clinical Trial Agreements and/or study protocols required Tellus, in turn, to pay individual study subjects directly for their participation in the clinical trial. Tellus was generally required to pay study subjects upon successful completion of an office visit required by the study protocol.

COUNT 1
Conspiracy to Commit Mail and Wire Fraud
(18 U.S.C. § 1349)

1. The General Allegations section of this Indictment is re-alleged and incorporated as though fully set forth herein.

2. Beginning in or around February 2014 and continuing at least through in or around July 2016, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendants,

MARTIN VALDES,
FIDALGIS FONT,
JULIO LOPEZ, and
DUNIEL TEJEDA,

did willfully, that is, with the intent to further the objects of the conspiracy, and knowingly combine, conspire, confederate, and agree with each other and with others known and unknown to the Grand Jury, to commit certain offenses against the United States, that is:

(a) knowingly, and with the intent to defraud, devise and intend to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing that the pretenses, representations, and promises were false and fraudulent when made, and, for the purpose of executing such scheme and artifice, did knowingly cause to be delivered certain mail matter by the United States Postal

Service and by commercial interstate carrier, according to the directions thereon, in violation of Title 18, United States Code, Section 1341; and

(b) knowingly, and with the intent to defraud, devise and intend to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing that the pretenses, representations, and promises were false and fraudulent when made, and, for the purpose of executing the scheme and artifice, did transmit and cause to be transmitted by means of wire communication in interstate and foreign commerce, certain writings, signs, signals, pictures, and sounds, in violation of Title 18, United States Code, Section 1343.

PURPOSE OF THE CONSPIRACY

3. It was the purpose of the conspiracy for the defendants and their co-conspirators to unlawfully enrich themselves by securing contracts to conduct clinical research trials, and causing sponsors and/or CROs to make payments on those contracts, by making material false and fraudulent representations regarding, among other things, subject eligibility for and participation in clinical trials.

MANNER AND MEANS OF THE CONSPIRACY

The manner and means by which the defendants and their co-conspirators sought to accomplish the objects and purpose of the conspiracy included, among other things, the following:

4. **MARTIN VALDES** and Tellus entered into Clinical Trial Agreements with sponsors and CROs, in which **VALDES** and Tellus agreed to conduct various clinical research trials, including the opioid dependency trials, the IBS trials, and the diabetes trial. As part of those agreements, **VALDES** and Tellus agreed to conduct the clinical research trials according to and in compliance with the study protocols and all applicable laws and regulations.

5. To inflate the payments received from sponsors and/or CROs under the Clinical Trial Agreements, Defendants and their co-conspirators falsified the participation of study subjects in clinical trials. Defendants and their co-conspirators entered false information in the case histories of clinical trial subjects to make it appear that the subjects had, among other things, satisfied the eligibility criteria to participate in a specific clinical trial, provided informed consent to participate in a specific clinical trial, received a physical examination from a principal investigator and sub-investigator at Tellus in relation to a specific clinical trial, received and been administered a study drug, completed laboratory tests and patient assessments required by study protocols, reported data as required by study protocols, and received payment for visits to Tellus as part of the clinical trial.

6. Defendants and their co-conspirators recruited and enrolled subjects in clinical trials that they knew did not meet the eligibility criteria set forth in the study protocols, including subjects that they knew did not suffer from the medical condition or conditions intended to be treated by the study drug.

7. Defendants and their co-conspirators obtained and used personally identifiable information of third parties, including copies of identification documents such as drivers' licenses and passports, to enroll and falsely portray individuals as participants in clinical trials at Tellus. For example:

a. **FIDALGIS FONT**, **JULIO LOPEZ**, and Person 2 obtained personally identifiable information from third parties, including friends and family members, which they used to portray those third parties as participants in clinical trials at Tellus although the third parties did not, in fact, participate in a clinical trial at Tellus.

b. In some instances, **JULIO LOPEZ** and Person 2 obtained identification

information from third parties without their knowledge or consent. **LOPEZ**, Person 2, and their co-conspirators used the third parties' personally identifiable information to portray those third parties as participants in clinical trials at Tellus without their knowledge, consent, or participation in the clinical trial.

8. Defendants and their co-conspirators falsely represented that study subjects had taken or been administered the study drug. In reality, Defendants and their co-conspirators discarded, without using, study drugs provided by the sponsors and required to be administered to the subjects under the study protocols.

9. **MARTIN VALDES**, Person 3, and their co-conspirators falsely represented in case histories that the principal investigator or sub-investigator performed physical examinations of study subjects, as required by the applicable study protocol.

10. Defendants and their co-conspirators falsified laboratory tests and patient responses required by the study protocol. For example:

a. The study protocol for the IBS trials required that blood samples be collected from study subjects during specified office visits and sent for laboratory testing and analysis. **JULIO LOPEZ**, Person 1, Person 2, Person 4, and their co-conspirators drew blood from employees of Tellus, sent the blood samples to a third-party laboratory for analysis, and received the blood test results back from the lab. **LOPEZ**, Person 1, Person 2, Person 4, and their co-conspirators then falsely represented in case histories of subjects in the IBS trials that the blood test results were those of the subjects in the IBS trials;

b. The study protocol for the IBS trials required subjects enrolled in the study to place daily telephone calls into an e-diary system, enter a confidential personal identification number specific to the subject, and answer questions to assess the subjects' drug usage, symptoms,

and experience. **DUNIEL TEJEDA**, Person 1, Person 2, and their co-conspirators placed telephone calls to the e-diary system and answered questions required by the study protocol in the IBS trials in place of, and without the knowledge of, the study subjects enrolled in the IBS trials. Defendants and their co-conspirators provided false and fictitious answers in response to questions about, among other things, the subjects' daily drug usage and experience.

11. Defendants and their co-conspirators created false records indicating that study subjects received checks compensating them for their participation in the clinical trial. For example:

a. Defendants and their co-conspirators placed into subject case histories photocopies of checks made out from Tellus to the study subject. The checks purported to compensate the subject for his or her participation in the clinical trial, as specified in the applicable study protocol.

b. **JULIO LOPEZ**, Person 1, Person 2, Person 4, and their co-conspirators signed payment logs in subject case histories indicating that the subjects received checks on certain dates when, in fact, they had not.

c. In some cases, **JULIO LOPEZ**, **DUNIEL TEJEDA**, Person 1, Person 2, Person 4, and their co-conspirators deposited checks, made out to a study subject and purporting to compensate him or her for participating in a clinical trial, into personal bank accounts owned and controlled by the defendants and their co-conspirators.

12. Defendants and their co-conspirators sent and received emails relating to conducting clinical trials at Tellus, including emails relating to the administration of study drugs.

13. **MARTIN VALDES** and Tellus entered into Clinical Trial Agreements directing sponsors and/or CROs to make payments for clinical trials by (a) transferring funds electronically

to bank accounts controlled by **FIDALGIS FONT**; and (b) mailing checks to Tellus's offices located in the Southern District of Florida. Those checks were subsequently deposited into a bank account controlled by **FONT**.

14. **FIDALGIS FONT** used the money received from sponsors and/or CROs for her own personal benefit, including, among other things, luxury items, personal travel, residential real estate, and a personal vehicle. **FONT** also used the money received from sponsors and/or CROs to compensate **MARTIN VALDES**, **JULIO LOPEZ**, **DUNIEL TEJEDA**, Person 1, Person 2, Person 3, Person 4, and their co-conspirators for their participation in the conspiracy.

15. To induce sponsors and/or CROs to enter into Clinical Trial Agreements with and provide money to the defendants and their co-conspirators, the defendants and their co-conspirators made and caused others to make numerous materially false and fraudulent statements to sponsors, CROs, and/or the FDA, including, among other things, the following:

Materially False Statements

(a) That **MARTIN VALDES** and Tellus conducted clinical trials, including the opioid dependency trials, the IBS trials, and the diabetes trial, in accordance with the study protocols applicable to each respective clinical trial;

(b) That enrolled study subjects satisfied the eligibility criteria for participating in clinical trials, including the opioid dependency trials, the IBS trials, and the diabetes trial;

(c) That **MARTIN VALDES** and a sub-investigator conducted physical examinations of subjects participating in the opioid dependency trials, the IBS trials, and the diabetes trial;

(d) That Tellus staff dispensed or administered the study drug to subjects enrolled in the opioid dependency trials, the IBS trials, and the diabetes trial;

(e) That subjects enrolled in the IBS trials provided blood samples;

(f) That subjects enrolled in the IBS trials placed telephone calls to the e-diary system; and

(g) That Tellus staff disbursed checks to compensate subjects for participation in clinical trials, including the IBS trials and the diabetes trial.

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

COUNTS 2-3
Mail Fraud
(18 U.S.C. § 1341)

1. The General Allegations section of this Indictment is re-alleged and incorporated by reference as though fully set forth herein.

2. From in or around February 2014, through in or around July 2016, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendants,

MARTIN VALDES,
FIDALGIS FONT,
JULIO LOPEZ, and
DUNIEL TEJEDA,

did knowingly, and with the intent to defraud, devise and intend to devise a scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing that the pretenses, representations, and promises were false and fraudulent when made, and, for the purpose of executing such scheme and artifice, did knowingly cause to be delivered certain mail matter by the United States Postal Service and by commercial interstate carrier, according to the directions thereon, in violation of Title 18, United States Code, Section 1341.

PURPOSE OF THE SCHEME AND ARTIFICE

3. It was the purpose of the scheme and artifice for the defendants and their accomplices to unlawfully enrich themselves by securing contracts to conduct clinical research

trials, and causing sponsors and/or CROs to make payments on those contracts, by making material false and fraudulent representations regarding, among other things, subject eligibility for and participation in clinical trials.

THE SCHEME AND ARTIFICE

4. The Manner and Means Section of Count 1 is repeated, re-alleged, and fully incorporated herein as a description of the scheme and artifice.

USE OF THE MAILS

5. On or about the date enumerated as to each count below, the defendants, as specified in each count below, for the purpose of executing and in furtherance of the aforesaid scheme and artifice to defraud and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises, knowing the pretenses, representations, and promises were false and fraudulent when made, did knowingly cause to be delivered certain mail matter by the United States Postal Service, according to the directions thereon, as more particularly described below:

COUNT	APPROXIMATE DATE	DEFENDANTS	DESCRIPTION OF MAILING
2	April 21, 2016	**MARTIN VALDES, FIDALGIS FONT, JULIO LOPEZ,** and **DUNIEL TEJEDA**	Check #5437 sent via U.S. mail from the sponsor of the diabetes trial, located in Chapel Hill, North Carolina, to Tellus, located in the Southern District of Florida
3	July 25, 2016	**MARTIN VALDES** and **FIDALGIS FONT**	Check #5461 sent via U.S. mail from the sponsor of the diabetes trial, located in Chapel Hill, North Carolina, to Tellus, located in the Southern District of Florida

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

COUNT 4
Money Laundering
(18 U.S.C. § 1956(a)(1)(B)(i))

1. The General Allegations section and Paragraphs 4 through 15 of Count 1 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

2. On or about May 6, 2016, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendant,

MARTIN VALDES,

did knowingly conduct and attempt to conduct a financial transaction affecting interstate commerce, that is, the deposit of funds in the approximate amount of $5,276 from Tellus into JP Morgan Chase Bank N.A. account number x5808 in the name of Futurox Research Consulting Corp, which financial transaction involved the proceeds of specified unlawful activity, knowing that the property involved in the financial transaction represented the proceeds of some form of unlawful activity, and knowing that the transaction was designed, in whole and in part, to conceal and disguise the nature, the location, the source, the ownership, and the control of the proceeds of specified unlawful activity.

It is further alleged that the specified unlawful activity is mail fraud, in violation of Title 18, United States Code, Section 1341, and wire fraud, in violation of Title 18, United States Code, Section 1343.

In violation of Title 18, United States Code, Sections 1956(a)(1)(B)(i) and 2.

COUNT 5
Money Laundering
(18 U.S.C. § 1957(a))

1. The General Allegations section and Paragraphs 4 through 15 of Count 1 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

2. On or about February 28, 2016, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendant,

FIDALGIS FONT,

did knowingly engage and attempt to engage in a monetary transaction affecting interstate commerce by, through, and to a financial institution, in criminally derived property greater than $10,000, that is, the negotiation of check number 2543, in the approximate amount of $35,000, drawn on the account of Tellus ending in 3770 at JP Morgan Chase Bank N.A. and made payable to Land Rover South Dade, such property having been derived from specified unlawful activity.

It is further alleged that the specified unlawful activity is conspiracy to commit mail fraud and wire fraud, in violation of Title 18, United States Code, Section 1349, mail fraud, in violation of Title 18, United States Code, Section 1341, and wire fraud, in violation of Title 18, United States Code, Section 1343.

In violation of Title 18, United States Code, Sections 1957 and 2.

COUNT 6
False Statements
(18 U.S.C. § 1001(a)(2))

1. The General Allegations section of this Indictment is re-alleged and incorporated by reference as though fully set forth herein.

2. On or about April 6, 2016, in Miami-Dade County, in the Southern District of Florida, in a matter within the jurisdiction of the United States Food and Drug Administration, an agency of the executive branch of the United States Government, the defendant,

MARTIN VALDES,

did knowingly and willfully make a false, fictitious, and fraudulent statement and representation as to a material fact, in that the defendant stated to an investigator with the United States Food and

Drug Administration that he personally performed a physical examination on each subject in the IBS trials for whom his signature appeared on the physical examination form in the subject's case history, when in truth and in fact, and as the defendant then and there well knew, he had not conducted such a physical examination, in violation of Title 18, United States Code, Section 1001(a)(2).

FORFEITURE
(18 U.S.C. §§ 981(a)(1)(C) and 982(a)(1))

1. The allegations of this Indictment are hereby re-alleged and by this reference fully incorporated herein for the purpose of alleging forfeiture to the United States of America of certain property in which the defendants, **MARTIN VALDES, FIDALGIS FONT, JULIO LOPEZ,** and **DUNIEL TEJEDA,** have an interest.

2. Upon conviction of a violation of, or a conspiracy to violate, Title 18, United States Code, Sections 1341 and/or 1343, as alleged in this Indictment, any defendant so convicted shall forfeit to the United States, pursuant to Title 18, United States Code, Section 981(a)(1)(C), any property, real or personal, which constitutes or is derived from proceeds traceable to such violation.

3. Upon conviction of a violation of Title 18, United States Code, Sections 1956 and/or 1957, as alleged in this Indictment, any defendant so convicted shall forfeit to the United States, pursuant to Title 18, United States Code, Section 982(a)(1), any property, real or personal, involved in such offense, and any property traceable to such property.

4. Forfeiture Money Judgments: The property subject to forfeiture as a result of the alleged offenses includes, but is not limited to, a sum of money equal in value to the total amount of funds involved in or derived from the alleged offenses and may be sought as a forfeiture money judgment.

5. Substitute Assets: If any of the property subject to forfeiture, as a result of any act

or omission of the defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third person;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be subdivided without difficulty,

the United States shall be entitled to the forfeiture of substitute property under the provisions of Title 21, United States Code, Section 853(p).

All pursuant to Title 18, United States Code, Sections 981 and 982(a)(1), and the procedures set forth in Title 21, United States Code, Section 853, as incorporated by Title 18, United States Code Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

A TRUE BILL

FOREPERSON

ARIANA FAJARDO ORSHAN
UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

GUSTAV W. EYLER
DIRECTOR
CONSUMER PROTECTION BRANCH
U.S. DEPARTMENT OF JUSTICE

LAUREN M. ELFNER
JOSHUA D. ROTHMAN
TRIAL ATTORNEYS
CONSUMER PROTECTION BRANCH
U.S. DEPARTMENT OF JUSTICE