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### Fake Histories, Calls by Staff Impersonating Subjects: A Look Inside Two Trial Fraud Cases

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By Theresa Defino

The trial was to be like any other that the clinical research organization (CRO) would oversee. The six-month study, known as VESTRI, would involve pediatric patients from age four to 11 who would receive one of two medications already approved for asthma, alone or in combination.

After their parents signed informed consent documents, the GlaxoSmithKline (GSK) protocol called for the children to have a screening visit, be randomized into the trial, and receive treatment appropriate to their level of symptoms.

To ensure they were closely monitored, the children were to “visit the clinic after two weeks, two months, four months, and six months,” and on a daily basis, their parents were to call an interactive voice response system “to record data about their asthma symptoms.” They also were to “speak with study staff by telephone at one month, three months, and five months post-randomization.”

As spelled out in court documents reviewed by RRC, that was the way it was supposed to work with Dr. Yvelice Villaman-Bencosme, who called her Pembroke Pines, Florida, pediatric practice Sacred Heart Medical Office PA. Perhaps Villaman-Bencosme had a special affinity for the children who were to be in the study—she herself has asthma that requires medication, Villaman-Bencosme would later testify during a hearing on her guilty plea.

Villaman-Bencosme contracted with the CRO in the fall of 2013, stating she would conduct the study from Unlimited Medical Research LLC, her facility in Miami. Her staff ultimately enrolled 107 patients in the study, for which they were paid \$455,214.

But nothing went the way it was supposed to. Villaman-Bencosme is now in prison for 63 months and two of her coworkers are as well, with sentences ranging from 14 to 30 months.<sup>[1]</sup> A fourth employee pleaded guilty last month and is awaiting sentencing this spring, and a fifth recently pleaded guilty.

Yet the crimes committed by Villaman-Bencosme and her coworkers are not unique—not nationwide nor even in Miami.

In fact, just last month, for part of his role in clinical trial fraud perpetrated by Tellus Clinical Research, also in Miami, Duniel Tejeda was sentenced to serve 30 months in prison and pay \$2.1 million in restitution.<sup>[2]</sup>

A former project manager and study coordinator, he joins two other former Tellus employees—Eduardo Navarro and Nayade Varon—who were sentenced in August 2021 to 46 and 30 months in prison, respectively, in connection with falsified trial data and given the same restitution requirement.<sup>[3]</sup>

It is not known whether there was any connection between the two research organizations, but the techniques used in the frauds are remarkably similar. The cases show the level of deceptions that may occur—as well as the consequences if they are discovered by the federal government, whose officials recently have said prosecuting

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clinical trial fraud—wherever it exist—is a priority. The cases also show the need for large sponsors of research, such as universities, to understand—and mitigate—the risks posed by smaller sites.

The Unlimited Medical Research case appears to go back somewhat further than Tellus Research’s, but the frauds occurred during roughly the same periods.

After contracting with the CRO, from 2013 to 2017, Villaman-Bencosme was aided by Lisett Raventos, the study coordinator; Maytee Lledo, the practices’ long-time receptionist; and Jessica Palacio, who also had the title of study coordinator. Villaman-Bencosme and Raventos were both sentenced in March.

These individuals fabricated case histories based on data from the Sacred Heart patients for the purported trial, and accepted the study drugs but never administered them. They pocketed the payments from GSK and the money that was supposed to be paid to the participants.

“Dr. Bencosme and her co-conspirators deliberately, artfully, and repeatedly lied about the medical treatment and study participation of children. They invented official-sounding statements to write in numerous fabricated case histories,” the government said in its sentencing memorandum for Villaman-Bencosme.

## **Government: Families’ Trust Was Abused**

“Critically, the success of the conspiracy depended upon the trust that Dr. Bencosme had built up with the parents of her pediatric patients,” the sentencing memorandum explains. “Parents were generally told that all they needed to do was sign the informed consent paperwork and do nothing more, and the parents typically completed this paperwork during a routine doctor’s appointment at the medical practice of Dr. Bencosme, a person whom they trusted as their child’s pediatrician.”

The parents made none of the required calls because their children weren’t really in a study. Instead, using the private information about the patients, Lledo herself “made all or virtually all of the phone calls...from her work phone, at her desk at Bencosme’s private medical practice...in full view” of the physician, according to the memorandum.

“While parents of some of these patients had a vague understanding that their child’s information was being used in drug research study of some kind, the parents did not understand their children to be actual participants in a clinical trial, with all that a clinical trial entails, and that their children did not in fact participate in the Unlimited Medical Research clinical trial,” the government said in its sentencing memorandum about Villaman-Bencosme.

There was some disagreement over how many calls Lledo made—hundreds or thousands—but they were numerous. As did the fraud, the calls “went on, day after day, for years,” pointed out Joshua Rothman, a trial attorney with the Department of Justice (DOJ) Consumer Protection Branch, according to a transcript of Lledo’s sentencing hearing.

Lledo’s attorney unsuccessfully argued that Lledo, who had worked for Villaman-Bencosme since 1996, played only a “minor role” in the fraud and deserved probation. She was sentenced to 14 months in prison and two years’ probation and was required to pay \$18,000 in restitution.<sup>[4]</sup>

## **CRO ‘Noticed Some Irregular Patterns’**

The scheme was apparently uncovered by the unidentified CRO—but it is not clear when that happened, and the FDA didn’t get involved until 2017, it appears. According to the government’s sentencing memorandum for Villaman-Bencosme, the CRO, “to its credit, noticed some irregular patterns in the reported data from Unlimited

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Medical Research, and notified the pharmaceutical company Sponsor of its concerns.”

GSK “reported the matter to the FDA and excised the data from what was ultimately reported to the FDA and published in scientific journals,” the memo states, adding that “this fraud was interdicted before faulty data was submitted to FDA or relied upon by practitioners.”

In addition to the 63-month prison sentence, Villaman-Bencosme’s plea agreement, which she signed Aug. 27, 2020, bans her from ever participating in a clinical trial and to pay restitution of \$174,000. She could have been sentenced to up to 20 years in prison.

Palacio was indicted later than the others, and her case has not progressed as far. In May, the DOJ announced she had been indicted on charges of conspiracy to commit wire fraud and making a false statement to an FDA investigator.<sup>[5]</sup> She does not appear have a sentencing date.

The most recent development in the case is a guilty plea by a fifth person connected to the case who was not previously mentioned in court pleadings and DOJ announcements.

On Jan. 12, DOJ announced that Olga Torres, described as the co-owner of the Miami research facility, “admitted that she knowingly lied” to the FDA during a Feb. 24, 2017, inspection.<sup>[6]</sup> “Specifically, Torres admitted that she falsely portrayed the clinical trial as having been conducted legitimately and honestly, when in fact Torres knew that certain data associated with the clinical trial had been falsified.”

She is scheduled to be sentenced April 13 and faces up to 20 years in prison and possible fines or restitution requirements.

## **Money Laundering Also Alleged**

It is not clear how—or when—the Tellus fabrications were discovered, nor how many alleged study participants were involved. But the three individuals who have pleaded guilty and are already sentenced are not the only ones to be charged with crimes related to the trial fraud.

Tejeda, Navarro and Varon, as noted, have already been sentenced in connection with the fraud at Tellus Medical Clinical Research; three others are awaiting trial.

In announcing their June 2021 guilty pleas, the government said Navarro and Varona admitted that they “agreed with one another and others to falsify data in medical records in connection with two clinical trials intended to evaluate a treatment for irritable bowel syndrome (IBS). Among other things, Navarro and Varona falsified data to make it appear as though subjects were participating in the trials when, in truth, they were not.”<sup>[7]</sup>

Three other individuals involved have pleaded not guilty and are facing a jury trial this summer. They are Julio Lopez, a Tellus study coordinator; Dr. Martin Valdes, a principal investigator; and Fidalgis Font; all purported to conduct studies from 2014 to 2016.<sup>[8]</sup>

Font is described by the government as the “owner of the business,” while Tejeda and Lopez were called “senior Tellus employees.” Each was charged with “conspiracy to commit mail and wire fraud and at least one substantive count of mail fraud,” the government said. “In addition, Valdes and Font were charged with money laundering and Valdes was further charged with making a false statement to inspectors” with the FDA.

## **Participants’ Daily Calls Also Fabricated**

The February 2021 indictment accused Font of paying \$35,000 five years earlier for the purchase of a Land Rover.

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Tellus was involved with far more trials than was the other clinic. Tellus was hired to conduct two opioid dependency trials, two related to treatments for IBS and diabetic retinopathy, according to the indictment.

Like the other clinic, Tellus employees are also accused of fabricating participants in the trials and falsifying medical histories. They also reportedly enrolled ineligible friends and family members and stole the identities of other people to enroll them as participants in the trials. Study medications were never administered and were discarded.

Clinic staff allegedly drew blood from Tellus employees and sent them to a lab claiming they were from individuals in the IBS study. Like with the asthma research, participants in Tellus' studies were to "place daily telephone calls into an e-diary system, enter confidential, personal identification numbers specific to the subject, and answer questions to assess the subject's usage, symptoms and experience," according to the indictment.

Valdez's alleged false statement was made to an FDA official on April 6, 2016, when he claimed to have "personally performed a physical examination on each subject in the IBS trials for whom his signature appears on the physical examination form in the subject's case history."

Lopez, Valdes and Font are to be tried together; their two-week jury trial is scheduled for May 31, according to an order signed on Dec. 3 by U.S. District Judge Robert Scola Jr.

The government noted that "if convicted of conspiracy to commit mail and wire fraud or mail fraud, each defendant faces a maximum penalty of 20 years' imprisonment. If convicted of money laundering, Valdes faces a maximum penalty of 20 years' imprisonment, and Font faces a maximum of 10 years' imprisonment. If convicted of making a false statement to the FDA, Valdes faces a maximum of five years' imprisonment."

## **DOJ: Expect Further Action**

The two Miami cases "represent only a sample of the branch's clinical trial fraud enforcement efforts, and we expect to bring further actions in the coming months," said Arun G. Rao, deputy assistant attorney general.

Speaking at the Food & Drug Law Institute's 2021 Enforcement, Litigation and Compliance Conference at the end of last year, Rao said DOJ's Consumer Protection Branch is continuing to focus on clinical trial fraud.<sup>[9]</sup>

"Fraud in clinical trials poses significant risks to the American public. The FDA relies on the veracity of clinical trial data when making drug approval determinations, with the ultimate goal of ensuring that all FDA-approved drugs are safe and effective for their approved indications," Rao said. "Fabricated clinical trial data can have dangerous consequences if relied upon by the FDA, drug researchers and medical doctors when making material decisions about the safety, efficacy and clinical use of drug products."

Added Rao: "In addition to specific harms attendant to a particular drug study in which data is fabricated, the existence of clinical trial fraud may serve to undermine confidence in the healthcare industry as a whole."

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<sup>1</sup> Department of Justice, "Medical Doctor and Study Coordinator Sentenced to Prison in Scheme to Falsify Clinical Trial Data," news release, March 22, 2021, <https://bit.ly/33BYm2E>.

<sup>2</sup> Department of Justice, "Florida Study Coordinator Sentenced in Scheme to Falsify Clinical Drug Trial Data," news release, January 20, 2022, <https://bit.ly/3FNTODE>.

<sup>3</sup> Department of Justice, "Clinical Researchers Sentenced in Connection with Scheme to Falsify Drug Trial Data," news release, August 11, 2021, <https://bit.ly/3KFdcWv>.

<sup>4</sup> Department of Justice, "Current and Recent Cases," Prescription Drugs and Medical Devices, United States v. Palacio, Case No. 1:21-cr-20301 (S.D. Fla. May 2021), <https://bit.ly/3KNEp9R>.

- 5** Department of Justice, “Study Coordinator Charged in Scheme to Falsify Clinical Trial Data,” news release, May 11, 2021, <https://bit.ly/3HaU4xL>.
- 6** Department of Justice, “Florida Co-Owner of Clinical Trial Company Pleads Guilty to Obstructing FDA Inspection,” news release, January 12, 2022, <https://bit.ly/3qSvc80>.
- 7** Department of Justice, “Clinical Researchers Plead Guilty in Connection with Scheme to Falsify Drug Trial Data,” news release, June 8, 2021, <https://bit.ly/3GXtN5E>.
- 8** Department of Justice, “Doctor, Clinic Owner and Staff Charged with Falsifying Clinical Trial Data,” news release, March 8, 2021, <https://bit.ly/3qRtvb4>.
- 9** Department of Justice, “Deputy Assistant Attorney General Arun G. Rao Delivers Remarks at the Food & Drug Law Institute’s (FDLI) 2021 Enforcement, Litigation and Compliance Conference,” news release, December 9, 2021, <https://bit.ly/3AsbvqE>.

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