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# 'If Only She Could Have Been Stronger': Miami Trial Fraud Leads to Prison, Personal Loss

By Theresa Defino

In September 2015, while working in an office on the grounds of Mercy Hospital in Miami, Ivette Maria Portela Martinez learned about an upcoming clinical trial for treatment of symptoms of Clostridium difficile infections and decided that AMB Research Center Inc. (AMB)—where she played many roles, including recruiter and pharmacist—should participate.

But Portela had a problem: She needed a doctor to sign on as the principal investigator (PI) for the trial sponsored by Actelion Pharmaceuticals and run by the clinical research organization (CRO) Pharmaceutical Product Development (PPD). Portela's husband, AMB co-owner Miguel Angel Montalvo Villa, had not practiced medicine since leaving Cuba in 2011, and his business partner, Bernardo Garmendia, AMB's vice president and backup study coordinator, had no medical training at all.

Portela set her sights on Angela Maria Giron, M.D. (pronounced Hur-own), an infectious disease specialist whose practice was adjacent to Mercy. Three times that month, Portela "approached Giron at a café in her office building" and discussed AMB, her husband and "clinical trial opportunities," according to court documents reviewed by *RRC*. At the end of September of that year, Giron met with Portela, Montalvo and Garmendia, learned about the trial, and sometime soon afterward, agreed to be the PI on the Clostridium difficile-associated diarrhea (CDAD) trial.

A week before they met, unbeknownst to Giron, Montalvo falsified Giron's resume to indicate that she had been employed by AMB since 2014 and had clinical trial experience—the first of many fabrications that would later come to light. Portela emailed the doctored resume to PPD, indicating that Giron was working with AMB. The next month, Portela assured Giron the trial would have no more than eight participants and would conclude in 2016.

In fact, the trial didn't start until 2016, at which time AMB faced another problem: finding participants with the type of diarrhea the study drug was designed to treat. Giron—whose practice was busier than it had been a year earlier—had already said she couldn't recruit her own patients and pointed out that Montalvo, by his own admission, was the one in charge.

Montalvo, Portela and Garmendia's solution was to dip into their database from previous trials, screen and pay family and friends and even use their own stool and blood samples—fabricate the data, hide the falsehoods from Giron (and the CRO) and get her to unwittingly sign off on the fraud.

Their scheme worked—but only for a while because concerns prompted an audit and an investigation by the Food and Drug Administration (FDA). Exposed was the grand—and perhaps sloppy—scale of their fraud. Among the red flags was that the data for the "randomized" participants was nearly identical. In October 2022, the three AMB employees and Giron were arrested on related charges in a case that echoes two recent others also involving Miami investigators.[1]

On Sept. 5, 2023, a jury convicted Montalvo and Portela on all charges: one count each of conspiracy to commit wire fraud and wire fraud, and for Montalvo, a third charge of making a false statement to an FDA investigator. In November, Montalvo was sentenced to 71 months in prison (based on a range of 57 to 71 months) and Portela to 46 months, the Department of Justice announced.[2] Garmendia, initially sentenced to 33 months after pleading guilty, testified against Montalvo and Portela in an arrangement that saw his time reduced to 22 months due to his cooperation.

## No Jail Time for Giron

Giron, who pleaded guilty to one charge of conspiracy to commit an offense against the United States, was facing 30 to 37 months in prison. Federal prosecutors requested prison time of 12 months fewer than the range, due to her cooperation, which included her testimony in Montalvo and Portela's trial.

Barry Wax, Giron's attorney, successfully argued against jail time, armed with nearly a dozen heartfelt letters urging leniency in her case. Giron "won," Wax said, when U.S. District Judge Kathleen M. Williams in the Southern District of Florida sentenced her to four years' probation, repayment of the approximately $60,000 she was paid from AMB and 350 hours of community service.

Along with the other three, Giron is also jointly responsible for restitution of $277,920 to Actelion Pharmaceuticals, now part of Johnson & Johnson. Exact amounts are yet to be determined, Wax said.

Yet, in an extensive interview with *RRC*, Wax hastened to add that Giron's story is a tragedy, in large part because she had to give up practicing medicine—a fight he said isn't over yet. Although he declined to say where, Wax said Giron is still working in health care but is not seeing patients as a doctor. He also would not say where she is doing her community service.

Giron will endeavor to get her license back, Wax said. State law requires physicians and others licensed under the Florida Department of Health Board of Medicine to report being found guilty of any crime related to health care, and following an administrative process by the board, the result is likely a "mandatory revocation." Getting her license back "is a long shot," Wax said. But "we're not going to roll over and play dead."

The government would not let Giron plead guilty and keep her license, regardless of her level of cooperation, Wax said.

"We tried very, very hard. I did everything I possibly could to put her in a position where they would give her transactional immunity," Wax said. "The upper levels of the Department of Justice refused. It's very hard to get transactional immunity for people, especially doctors—they hold doctors to a very high standard."

Although, as called for in the plea agreement, Williams required Giron to relinquish her medical license "upon request of the appropriate regulatory agency," she placed no restrictions on her engagement in health care—something Wax said was unprecedented in his 39-year career. Giron's license was due to expire in January 2023, and she allowed it to lapse.

## Attorney: Judge Believed Others Used Giron

Williams "specifically said on the record at sentencing that she is not restricting her from working in the health care industry because she believes that she is a wonderful doctor who was taken advantage of by Montalvo, Portela and Garmendia in this case, [and] that she believed that, if she could gain employment within the health care field, she should," Wax said "That's the only time I've ever had anyone convicted of a health care-related crime that a judge has allowed that." In addition to jail time, Montalvo was sentenced to three years' probation.

During that time he cannot "participate in any manner" related to the issues in the trial.

Prosecutors requested, but Williams did not grant, a similar restriction on Giron. However, said Wax of Giron, "I can tell you that she has no intention of ever having anything whatsoever to do with clinical research trials."

According to court documents and Wax's statements to *RRC*, Giron hadn't considered engaging in research until Portela contacted her. A native of Colombia who completed medical school there and later a residency at the University of Pennsylvania and a fellowship at Jackson Memorial Hospital in Miami, Giron has been board-certified in internal medicine and infectious disease since 2007.

Wax told *RRC* that Montalvo and Portela "researched infectious disease doctors," found and then targeted Giron. Portela "approached her and introduced herself and made small talk and ultimately discussed with her the opportunity to conduct one of these studies as a principal investigator. And since it was in her field and [CDAD] was something she often dealt with, [the study] was attractive to her," Wax said. She reasoned it could perhaps provide some benefit to her patients, he added.

## Giron 'Lacked Strength' to Quit Study

Montalvo and Portela told Giron their firm had a history of successfully conducting trials. Clinicaltrials.gov shows AMB as the site for six studies, most starting in 2015, for glaucoma, acne, depression with psychosis, osteoarthritis of the knee and hip and two studies of agitation in Alzheimer's patients. Government court documents refer to AMB as a medical clinic.

When the study started a year later than promised, Giron "no longer had enough time to properly act" as the PI, Wax told *RRC.* Giron tried to end her involvement at that point; however, Montalvo—noting he had been a doctor in Cuba—convinced her that "she would be able to delegate responsibility to him to conduct the patient examinations, obtain the necessary samples, interview the patients for any adverse effects and other matters that were important to the study. And he would share that information with her, and she would be able to sign off on these things," Wax said.

Giron's personality, Wax said, "is such that she couldn't bring herself to be firm and withdraw from the study. She tried and Montalvo brought to bear a lot of persuasion and she succumbed. If she only could have been strong enough to stand her ground, this never would've happened to her."

He added that, in Giron's case, "most importantly, there was the issue of the reading of the informed consent to the patients, which was not delegable, but which unfortunately she did delegate. And that was really the linchpin of the case against her…the delegation of the informed patient consent."

It's not clear how many participants AMB enrolled in the trials, but as noted earlier, it expected only eight for the CDAD study. But that was proving difficult so the trio—under Montalvo's direction—"prepared falsified informed consent forms using the names and personal identification information" of individuals who had previously been screened and thus had no knowledge they were being potentially enrolled in the CDAD trial, government court records show. The AMB staff also used their own specimens and those of friends and family, some of whom were paid $120.

In total, AMB said 42 individuals had been screened and 22 were eligible. "When family and friends pretending to participate in the…clinical trial came to AMB's office, Portela Martinez sat down with them and told them what to write in the diaries" that were submitted to the CRO, the records show.

## 'Clinical Cure Reached at the Same Time'

Montalvo, Portela and Garmendia took numerous steps to keep Giron in the dark. Montalvo "led, organized, managed, and controlled nearly all events and communications with PPD and Actelion throughout the CDAD clinical trial," such as "sending an email to PPD stating he was the lead study coordinator who would manage the CDAD clinical trial."

Montalvo was PPD's "go-to person for questions about documents in patient files and binders, including missing documents." He also told Portela "to fabricate and falsify information on the stool diaries" and "instructed Garmendia to take hundreds of pages of CDAD clinical trial documents to Giron to sign," the government's sentencing memorandum for Montalvo states. He also "planned, organized, and prepared the clinical trial documents for Giron's signature, including placing stickers where Giron needed to sign so she would go directly to those pages and not review other parts of the documents."

At some point in 2017, "Actelion conducted an audit at AMB" for the trial, government documents show. "Actelion's concerns with AMB's clinical trial data included (1) all 22 randomized subjects reached clinical cure at approximately the same time; (2) the start of onset of diarrhea was almost the same for every randomized subject; (3) every randomized subject had the same number of bowel movements within 24 hours of randomization; (4) the drug kits, questionnaires, and diaries were neat and clean and showed no signs of use; (5) all medication sachets were opened in the same manner; and (6) the validity of the signatures on the informed consent forms."

Actelion then sent FDA "written notification of possible scientific misconduct by AMB."

In response to Actelion's letter, Montalvo drafted a response that Giron "knew…included false representations and that she had not consented all subjects," according to the government's sentencing memorandum concerning Giron. She also "added one paragraph regarding scientific literature" to the letter. Giron "signed the response letter because Montalvo Villa told her she would lose her medical license if she did not sign it."

FDA opened an investigation, making a site visit on Feb. 20, 2018. "On the first day of the inspection, [Montalvo] told the regulatory investigator…he was present when Giron had obtained all the informed consents" and that "copies of the informed consent were given to the subjects and he was the most responsible person at AMB."

Giron never suspected anything was amiss and "was shocked" to get the FDA letter, Wax said, and to "learn that the data had been falsified because from her perspective there was no way to falsify this data. She had been led to believe that there would be stool samples submitted and that genetic testing would reveal if the stool samples were not from discreet individual patients. And [investigators] were able to determine from what was presented, that [this] was, in fact, done fraudulently."

## Government: Giron 'Abdicated' Trial Duties

After consulting with Wax, Giron quickly acknowledged her role in the fraud and spent four-and-a-half years assisting the government in building the case against the others prior to her entering her own guilty plea.

"She's a very—was a very—dedicated doctor, and that's what makes this so tragic," Wax said. Her actions persuaded the government to allow her to keep practicing during the lengthy investigation, which gave her time to help patients find other care before she had to stop practicing, Wax said, adding that he did not know how many patients Giron had.

"The government was very considerate about that," he said. "She only had to start winding down her practice when we knew that it was going to come time for her to plead guilty."

However, in insisting on jail time, the government cited the need to send a message to others who might commit

clinical trial misconduct. *RRC* contacted government attorneys involved and other lawyers in the case, but none would comment.

"Numerous medical clinics, companies, and other institutions participate in clinical trials in the United States, including in the Southern District of Florida. There is a need to deter fraud by principal investigators and the trial sites in clinical trials to protect the integrity of the clinical trials process, new drug research, the drug approval process, and to protect consumers, the community, and the public health," the government's sentencing memorandum states.

The government also argued that Giron "abdicated her responsibilities as principal investigator for the CDAD clinical trial. She also abused her position of trust and used her specialized skill as a medical doctor."

Yet, letters submitted on her behalf and Wax's sentencing memorandum note Giron's character and her role in caring for patients, many without insurance, particularly during the pandemic.

As Raul Moas, M.D., Mercy's former director of critical care and respiratory medicine who worked with Giron for 12 years, wrote: "Beyond being an exceptional and thoroughly dedicated physician all her years at Mercy, and consequently very much in demand, it was during the initial 18 months of the COVID pandemic that her commitment to the profession really shone. In the major 'surges' that occurred from March 2020 through the latter part of 2021, Mercy was swamped beyond capacity with severe COVID cases, as were most other hospitals. While many physicians (including other infectious disease consultants) made themselves scarce, Dr. Giron stepped forward, along with one other infectious disease specialist, and was with us in the [intensive care units] every day, managing the complex medication regimens of these patients."

Now the community is "deprived" of a "brilliant infectious disease physician," Wax said. "A lot of people might not feel that way because of what happened, but she always had her patients' best interest at heart. And she felt a sense of obligation to the study."

## Warning for Potential PIs

Asked to identify any takeaways from the case, Wax said the "number one lesson…especially for a principal investigator, is don't delegate non-delegable things. If you agree to participate in a study, do your job. And if you're unable to do your job, step back and withdraw from the study. I think that's the primary thing. Don't bite off more than you can chew."

Wax added that while research fraud "is a problem, I don't think it's so prevalent that it's going to end up negating studies. I think that there's enough controls that are in place that between the CRO and the sponsor and the FDA, you can root out the fraud."

The majority of clinical research facilities, "especially on the university level…are doing legitimate research. And, typically, you're going to have that when you have doctors who are doing it as part of their offices who have patients who are participating in a study," said Wax. "You can always compare that data to data which is suspicious, and it'll assist you in making a determination of whether you've got fraud going on."

**1** Theresa Defino, "Fake Histories, Calls by Staff Impersonating Subjects: A Look Inside Two Trial Fraud Cases," *Report on Research Compliance* 19, no. 2 (February 2022), https://bit.ly/3TFQiF1.
**2** U.S. Department of Justice, Office of Public Affairs, "Florida Medical Clinic Owner and Pharmacy Technician Sentenced to Prison in Clinical Trial Fraud Scheme," news release, November 30, 2023, https://bit.ly/3IIssSS.