

## Report on Research Compliance Volume 21, Number 4. March 21, 2024

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

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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.<sup>[1]</sup>

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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.<sup>[2]</sup> 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.

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