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## South Florida doctors, hospitals named in fraud lawsuit

BY JOHN DORSCHNER

Federal authorities are conducting a criminal investigation into allegations that 25 South Florida doctors and a dozen hospitals engaged in an "elaborate scheme" in which the doctors received improper compensation for recommending or implanting pacemakers and defibrillators made by ELA Medical, an Italian company.

The investigation stems from a whistle-blower lawsuit, filed in 2006 by a former ELA employee. For almost three years, the accusations were kept out of the public record. They were recently ordered to be made public by U.S. District Judge Adalberto Jordan.

The lawsuit shines a new light on the much-criticized world of medical device sales, in which there have been repeated accusations of fraud. Some experts say such fraud is a major reason why Medicare healthcare costs in Miami are twice the national average.

U.S. attorney spokeswoman Alicia Valle said Friday afternoon that prosecutors were still studying the case and had not decided whether to intervene in support of the whistle-blower.

Many hospitals and doctors named in the complaint told The Miami Herald they didn't know about the lawsuit and had done nothing wrong. "This is 300 percent wrong," Miami cardiologist Manuel Franco said.

Bill Huron, an ELA spokesman, wrote in an e-mail that the company "welcomes the decision -- after three years of investigation -- of the Department of Justice not to intervene in the lawsuit at this time.

"ELA believes that the complaint contains no allegations of any substance against it and will defend any legal suit vigorously. . . . ELA is committed to the highest standards in business ethics and continues to cooperate fully with the Department of Justice."

### STUDY PAYMENTS

Tania Lee, the former employee, alleges that ELA rewarded doctors for using its devices with lavish trips to Europe and elsewhere, or by paying them for studies, at \$1,200 each, or bought them heart monitors that they could use to follow patients remotely and get reimbursed for their efforts by Medicare.

The lawsuit alleges that the scheme created "claims arising from services not allowable under law," meaning the federal government's Medicare program could have lost "millions of dollars."

Defibrillators can cost \$20,000 or more. Pacemakers go for \$5,000 to \$7,000. ELA, owned by Sorin Group, is one of the smallest device makers in the field, which is dominated by Guidant, Medtronic and St. Jude.

In the complaint, Lee, who was a technical services representative, said she went to some cardiologists' offices once a month to test pacemakers of patients. If the battery needed replacement, "the cardiologist would refer the patient to one of the listed physicians to replace the existing pacemaker with an ELA model. The cardiologist would bill Medicare for the cost of the test performed by Ms. Lee."

In Lee's view, the issue was that the doctors were not recommending an ELA device because it was the best, but because they were getting paid to recommend it. The lawsuit does not make any allegations about

endangering patients or installing unnecessary pacemakers.

One of the cardiologists named in the lawsuit, Humberto Machado Jr., was adamant that he had nothing to do with ELA. "I stayed away from them like the plague." He said the company's sales reps had a "really unsavory reputation," plying doctors with research funds, fancy dinners and trips.

Scott D. Matthison, a former ELA sales rep named in the lawsuit, said he did nothing wrong. Many device makers pay doctors for studies, to improve their research, he said. Some doctors were given trips to ELA's corporate parent in Milan, Italy, but that was simply for the doctors to learn more about the devices, Matthison said.

The other former salesman mentioned in the lawsuit, Shawn DeRosa, referred a reporter to his attorney, who did not return a call.

Much of the lawsuit concerns ELA's relationship with the cardiologists who recommend to surgeons what devices to implant. The procedures are generally done in hospitals. Baptist, Mount Sinai, Mercy, Larkin and Jackson, which are all named in the suit, said they had not seen the lawsuit and knew of no wrongdoing at their hospitals.

#### **`NO MERIT'**

"The lawsuit does not allege any improper conduct by Baptist Hospital or South Miami Hospital, and it appears to have no merit as applied to the hospitals," David R. Friedman, general counsel for Baptist Health South Florida, wrote in an e-mail.

Merill Davis, a spokeswoman for Tenet, which owns two hospitals named in the lawsuit, also said there are no specific charges against the hospitals: "We firmly believe that this case is without merit."

#### **`EUROPEAN CRUISE'**

In one specific allegation, cardiologist Handre Hurwitt was accused of participating in post-market studies of ELA devices. "He also went on a European cruise in April of 2005" with an ELA salesman. Vivian Arguez, office manager for Hurwitt, said he paid for the trip himself, met the salesman for only one day and didn't receive money from studies.

Cardiologist Humberto Machado Sr. said he may have done some research work for ELA, but that any money he received was "nominal" and did not influence him to recommend ELA devices.

Surgeon David Gabult said he could not comment on the lawsuit because he had not seen it, but "my actions are of the highest integrity."

Miami Beach cardiologist Fernando Sende, Coral Gables cardiac electrophysiologist John Dylewski and Fort Lauderdale surgeon Antonio Revilla said they never received any payments or other compensation from ELA.

Similar accusations against other device manufacturers have reverberated for years throughout the industry. In 2007, a federal investigation found that many orthopedic surgeons were getting hundreds of thousands of dollars a year for using companies' hip and knee implants. In that case, the device makers paid hundreds of millions of dollars in fines and were forced to publish lists of how much surgeons had received.

In March 2006, The New York Times reported that unnamed federal officials said authorities were investigating whether ELA provided improper incentives to doctors in the Miami area.

In May 2006, attorney Jon May filed the whistle-blower lawsuit on behalf of Lee. As is customary with such lawsuits, the complaint was sealed, meaning it was not entered into the public record, while the U.S. attorney's office investigated the allegations to see if it wanted to intervene in the case or not.

Some cases remain sealed until prosecutors decide to intervene or not. In the ELA case, they filed several requests for extension for more time, and so did attorney May. On Jan. 23, prosecutors filed a notice that their "investigation is not completed" and they couldn't decide ``whether to proceed with or to decline this action."

Judge Jordan noted that "no indictment has been filed," and it was in the interest of "the defendants, the court and the public" to unseal the case.

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