MEALEY'S LITIGATION REPORT

Diabetes Drugs

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# Jury Meant To Award Plaintiffs $26.2 Million

LIBERTY, Mo. — A Clay County Circuit Court jury was about to award $26.2 million to the plaintiffs in a Rezulin trial when the parties settled for an undisclosed amount Dec. 27 (Shirley Griggs, et al. v. Warner-Lambert Company, No. CV100 3957 CC, Mo. Cir., Clay Co.; See December 2001, Page 6).

Jury foreman Clark Lamoreux of Kansas City, Mo., said the jury had, by a 9-3 vote, decided on awards of $3.2 million in compensatory damages and $23 million in punitive damages when Judge James Welsh told them the parties had settled.

**'Smoking Gun'**

Lamoreux said the verdict was based on "smoking-gun" internal Warner-Lambert Co. documents that demonstrated "blatant disregard for public safety." He said the documents included high-level internal documents "that stated that this is a profit-driven company and they've got to do whatever they can to get Rezulin approved." Other documents, he said, showed how the company "deliberately misled the FDA and doctors." He said the focus of the jury's verdict was not Rezulin itself, which could have been a useful drug had its risks been fully disclosed. "The problem was, Warner-Lambert was not forthright in communicating the risks," he said.

Shirley Griggs, 67, of Edgerton, Mo., was a bank teller for 30 years. After she and her husband, Jerry, 69, retired in 1994, they bought a camper to travel the United States, according to her attorneys. She had some "fatty liver" and mild Type 2 diabetes but was otherwise in good health when she began taking Rezulin in June 1998. In fall 1998, she began to have symptoms of fatigue and nausea, but her liver tests were paradoxically the lowest they had ever been, according to her attorneys. In January 1999, she was diagnosed with liver failure and put on a transplant list. The plaintiffs said they put on evidence that Rezulin had been proved in a Warner Lambert study to mask elevated liver enzymes, especially in people with nonalcoholic steatohepatitis, which the defense argued caused Griggs' liver injury.

**Former FDA Official Testifies**

The plaintiffs had used extensive testimony from former FDA medical officer John Gueriguian, M.D. Gueriguian was key to the plaintiffs' contention that Warner-Lambert and the FDA knew of Rezulin's dangers early on and that the company manipulated the FDA into approval. Gueriguian had prepared a draft report in fall 1996, arguing against approval because of dangers to the liver and heart, according to the plaintiffs' complaint.

After Warner-Lambert complained of Gueriguian's behavior, his superiors at the FDA removed him from further consideration of Rezulin and did not show his draft report to the FDA committee evaluating Rezulin. Instead, Griggs' attorneys have argued, Gueriguian's superiors provided Warner-Lambert with a computerized copy of his report with the understanding that the company would edit it and remove portions it didn't like. Within three months of Gueriguian's removal, the FDA approved Rezulin as the first "fast-track" drug.

The plaintiffs are represented by Zoe Littlepage and Rainey Booth of Littlepage Booth in Houston and Pensacola, Fla.