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Diet drug lawsuit goes to trial

Jury hears testimony on risks

ollinses seek damages from Vyeth-Ayerst for medical costs

A woman who was responsible for compiling records of products' adverse side effects for a diet drug manufacturer said she classified a case in which a user experienced heart valve leakage as "non-serious" in the safety department's database.

That meant the company did not have to immediately report it to the U.S. Food and Drug Administration.

The official also said she suggested in June 1994 that the product's package insert be changed, because it stated there had been four cases of pulmonary hypertension reported when, by that time, the actual number was "different."

Rollins

But the insert was not changed until August 1997, she said.

Amy Myers, associate director of safety surveillance for the Wyeth-Ayerst Laboratories Division of American Home Products, made these statements in a videotaped deposition viewed by jurors Tuesday in a trial over health problems allegedly caused by the drug Pondimin.

The company withdrew the drug from the market at the request of the FDA in September 1997 after 24 women involved in a Mayo Clinic study developed heart valve problems. Eight had newly documented pulmonary hypertension and five needed open heart surgery to repair or replace damaged valves.

Dorothy Rollins, 51, and her husband, Eugene, 51, of rural Council Bluffs are seeking damages from Wyeth-Ayerst for her past and future medical costs and suffering and his suffering as her spouse, as well as punitive damages.

The suit is being tried in Pottawattamie County District Court.

The two sides' strategies began to take shape Tuesday as attorneys fired their opening volleys in a legal battle that is expected to last four to five weeks.

Myers' testimony was heard in response to questions by Rollins' attorneys as they attempted to demonstrate that company officials concealed information about the drug's risks as long as possible in order to maximize profits.

The FDA has no research budget and relies on pharmaceutical companies for information on adverse drug experiences, Rollins' attorney, Zoe Littlepage, told the jury.

"It's the responsibility of the company to pass this along to the FDA," she said.

Manufacturers must report "serious and unexpected" effects within 15 days, she said.

"This is a company that put profits over the safety of people," Littlepage said in her opening statement for the plaintiffs.

Brian Leitch, an attorney for American Home, said the package inserts were corrected by June 1996 to state there had been 95 cases involving pulmonary hypertension and the incidence was 18 per 1 million users.

He said the labeling change was delayed until a study designed to determine the risk was completed so that information could be included.

"When we got the incidence rate, we put it in the label and we sent it to the doctors," he said.

As sales increased, the incidence of pulmonary hypertension decreased, Leitch said. That made it unclear whether there was a connection between the drug and the symptom.

The product had been on the market for 20 years before there were reports of heart valve problems, he said. The number of cases increased during the early 1990s, but sales were increasing much faster.