The Legal Intelligencer

Amaris Elliott-Engel
2011 01-19

Judge in Avandia Litigation Opens Door to Plaintiffs' Experts

Litigation over a diabetes drug that allegedly causes heart problems has reached significant milestones with the federal multidistrict litigation judge ruling that the plaintiffs' experts pass scientific rigor and with more than 1,000 cases in Philadelphia Common Pleas Court settling for undisclosed amounts.

The plaintiffs suing drugmaker GlaxoSmithKline over alleged injuries from their use of Avandia argue that Avandia causes heart attacks, or myocardial infarctions, in diabetic patients taking the drug.

U.S. District Judge Cynthia M. Rufe of the Eastern District of Pennsylvania ruled earlier this month that the three plaintiffs' expert witnesses meet the Daubert standard for scientific validity.

"Although the conclusions differ from the conclusions reached by GSK's experts, generally speaking the epidemiological studies relied upon by plaintiffs' experts are the same studies consulted by GSK and the FDA [the federal Food and Drug Administration] in their evaluation of the risk profile of Avandia," Rufe wrote Jan. 3. "Plaintiffs' experts arrived at their conclusions that sound scientific evidence supports a causal inference without any speculative leap."

The plaintiffs' experts are Dr. Eliot A. Brinton, a diabetologist and lipidologist who works for the University of Utah School of Medicine; Dr. Allan D. Sniderman, a cardiologist who is a professor at McGill University in Montreal; and Nicholas P. Jewell, a professor of biostatistics at the University of California, Berkeley, Rufe said.

GSK argued that the randomized control trials relied upon in the experts' opinions show a statistically insignificant increase in atherosclerosis, or when fatty material collects along the walls of arteries and blocks the arteries, leading to heart attacks, Rufe said.

GSK also said one large randomized control trial showed no statistically significant increase in heart attacks, hospitalization because of heart problems or death, Rufe said.

But the plaintiffs' experts countered that the trial lacked "the power necessary to test the hypothesis" because the sample size was too small, Rufe said.

Of 23 observational studies, nine found a statistically significant increase in heart attacks for users of Avandia, 13 found no statistically significant correlation and one showed a "statistically significant protective effect," Rufe said.

The experts opined that Avandia users show an increase in low-density lipoprotein, which is a predictor of the risk of cardiovascular disease, Rufe said. Because patients taking Avandia also are often prescribed statins, the true effect of Avandia may be underestimated, Rufe wrote.

Avandia has been restricted in its use in the United States, and the drug's sales in Europe have been suspended completely, Rufe said.

"We are disappointed with this decision from the court, as we believe the opinions of the plaintiffs' experts are not based upon reliable scientific methodology," GSK spokeswoman Mary Anne Rhyne wrote in an e-mail. "It is important to note that this ruling simply means that the court will allow the jury to hear plaintiffs' experts' opinions in the courtroom."

In a ruling issued Tuesday in an upcoming trial, Rufe barred one plaintiff expert on specific causation but allowed in the other plaintiff expert.

In an unusual level of coordination, the hearings in September over the plaintiffs' experts led to Rufe hearing the cases along with Philadelphia Common Pleas Court Judge Sandra Mazer Moss, the coordinating judge of Philadelphia's mass torts program, the Complex Litigation Center.

Other state court judges either participated in the hearing through videoconference or will access the results of the hearing through transcripts, Rufe said.

There are state court judges from five states who are accessing information from the MDL.

"I think it's a really excellent management idea in mass torts. It means the attorneys only have to argue once," Moss said. She said the attorneys, at some points during the hearing, would separately address the Daubert scientific standard in federal court and the Frye scientific standard in Pennsylvania state court.

Moss said she has not yet issued her global Frye opinion because she has been focused on settling cases and all the cases set for trial have been settled so far. As of press time, a trial was scheduled for Jan. 31.

"Dealing with the judges from all over the country they are very appreciative of the MDL relieving them of the need to conduct discovery and try those cases," Rufe said. "I think the mediation efforts have really helped the state court jurisdictions."

Settlements

While there have been no bellwether trials held yet in the MDL based in Philadelphia or in Pennsylvania state court, cases have been settling on a law firm by law firm basis, according to interviews.

Rufe said the MDL has been proceeding on two tracks: mediation and a bellwether trial schedule. The next MDL bellwether trial, scheduled to start Jan. 24, involves a North Carolina plaintiff.

"We have not conducted separate mediations on a case-by-case basis because the inventory settlements or a matrix grid for the entire MDL is my thrust," Rufe said. "I am handling a total of 50,000 claims, filed and unfiled."

Settling cases based on a law firm's inventory has created a settlement posture in state courts, Rufe said.

Rufe said the Avandia MDL is larger than many other MDLs, noting a 2007 report that said only nine MDLs involved more than 1,000 cases.

Tolling agreements are in place with GSK in which the plaintiffs' attorneys do not have to file their cases, Rufe said.

The use of Jerome Shestack as a discovery master has kept the MDL from being bogged down, Rufe said. Rufe also holds the view that the MDL has gotten to the stage of bellwether trials at an unusual pace.

California state courts have the largest number of Avandia state court cases with 3,500 filed cases, Rufe said.

In Pennsylvania, 1,200 cases were filed and there are now less than 250 cases left after settlements, Moss said last week.

Sol Weiss, a plaintiffs attorney with Anapol Schwartz Weiss Cohan Feldman & Smalley and a plaintiff liaison counsel to the Avandia program in Philadelphia Common Pleas Court, said his firm settled its Avandia inventory.

While some plaintiffs' attorneys have disagreed with settling their inventories for the amounts being offered by GSK, "the money our clients were going to get was very fair in the circumstances," Weiss said. "There was and remains a very difficult causation question for the jury because diabetics are at an increased risk for having a heart attack. We had some cases where we thought we could do a real good job on causation and we had a lot of cases where we thought we could do less ... and when you have that mix there's a good cause to settle cases."

Plaintiffs attorney The attorneys negotiating for GSK include Nina M. Gussack of Pepper Hamilton in Philadelphia, George A. Lehner of Pepper Hamilton in Washington, D.C., and Michael K. Rozen, of Feinberg Rozen with offices in Washington, D.C., and New York City, according to interviews. Attorney Kenneth R. Feinberg, Rozen's partner, was involved in payouts for the victims of Sept. 11 and the Gulf oil spill.

"There are many circumstances where a company may determine to resolve certain matters in order to avoid the inherent risks and significant costs of litigation," Rhyne said in an e-mail. "... GSK continues to stand behind Avandia and defend its position in the litigation."

(Copies of the 32-page opinion in In re Avandia Marketing Sales Practices and Products Liability Litigation , PICS No. 11-0122, are available from The Legal Intelligencer. Please call the Pennsylvania Instant Case Service at 800-276-PICS to order or for information. Some cases are not available until 1 p.m.) •