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Johnson & Johnson loses first Levaquin case

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Ronald Goldser

The bell in the first Levaquin bellwether case tolled loudly for plaintiffs, but a few more trials will probably be required to truly judge the way the wind is blowing.

In the first trial regarding the effects of the antibiotic Levaquin, a Minneapolis federal jury this month awarded an Edina man $1.8 million. The case, Schedin v. Johnson & Johnson, et al., was brought by John Schedin, now 82, whose Achilles tendons ruptured in 2005 after he had taken the drug for three days for treatment of bronchitis.

The trial was the first of more than 2,600 other U.S. lawsuits making similar claims. A status conference on the multidistrict litigation is scheduled for January in Minneapolis, when a date for the next trial will be discussed.

Reasonable minds differ on the significance of a bellwether verdict for other cases, said Minneapolis litigator David Herr. Although bellwether cases provide one “data point” about the possible outcome of a case, sometimes the various cases in an MDL turn on individual facts, he said.

“In the history of mass torts, there have been a lot of paths that litigation has taken,” Herr said. “Sometimes one side wins a bunch of cases and then never wins again.”

But the theory behind a bellwether case is to set guidelines for the parties, predict likely outcomes of similar cases and gauge settlement values.

However, the cases are tried on different facts and before different judges, and the evidentiary rulings of one judge do not bind other judges, Herr pointed out. The MDL process is designed to coordinate pretrial matters, not trial rulings, he said.

The judge who receives the case for pretrial matters from the MDL panel is called the transferee judge, and the case is then remanded for trial to the original judge where the case was filed. Although the transferee judge could rule on motions in limine, the transferee judge is restrained about making rulings another judge will try, Herr said.

Failure to communicate

In 2008 Schedin sued Ortho-McNeil-Jansen Pharmaceuticals, the unit of New Brunswick, N.J.-based Johnson & Johnson that markets Levaquin. That same year, the Food and Drug Administration required Johnson & Johnson and makers of similar drugs to print, with the packaging of the drug, “Black Box” warnings on the risks of tendon injuries.

The jury awarded Schedin $700,000 in actual damages and $1.1 million in punitive damages, though actual

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damages will be reduced by $70,000 because the jury found the plaintiff 10 percent at fault. When he first felt the pain in his tendons, Schedin tried to alleviate it by exercising, thus contributing to the injury.

The key to victory was explaining to the jury what the case was really about, said the plaintiff's attorney, Ronald Goldser of Minneapolis.

"We were very much aware that the main issue was a failure to communicate," Goldser said.

The crux of the case, he said, was that the defendants didn't adequately present warnings of the dangers of Levaquin, especially to the elderly and to those taking steroids, as Schedin was for bronchitis. Although the company gave some warning, "They put it in the fifth page of a 14-page [package insert] in the middle of a paragraph in small type," Goldser said.

The company did nothing to draw attention to the warning, such as writing to doctors, giving seminars or instructing sales representatives to talk about it, Goldser said.

The plaintiff's argument about the warning gained traction when U.S. District Court Judge John Tunheim ruled admissible evidence of changes to the warning label after Schedin was prescribed the drug. Tunheim said that Rule 407, FRE, does not bar evidence of subsequent remedial measures required by a government agency. He further said the evidence was not prejudicial or pre-empted.

But the plaintiff didn't stop at calling the warning label inadequate. Facing a serious challenge to its labeling practices in Europe, Johnson & Johnson had its own epidemiological study performed in the United States.

Goldser said the study was "unscientific," and it contradicted the results of about 15 other studies. "That really caught the attention of the jury," he said.

According to Goldser, the defendant didn't really react to the plaintiff's attack on the study. "They defendant focused on what a great drug it is. They never really met us head on" about the results of the study, he said.

The defense also had a problem when Tunheim excluded parts of the testimony of one of its experts, Dr. J. Paul Waymack, an FDA consultant whose testimony had been excluded in other drug cases as unreliable, Goldser said.

Michael Heinley, spokesperson for Ortho-McNeil-Jansen Pharmaceuticals, said the company would not speculate about the reasons for the verdict but will vigorously defend the case on appeal.

Schedin was a carefully chosen plaintiff to propose for a bellwether trial, Goldser said. First of all, he is a resident of Minnesota so it was undisputed that Minnesota law would apply and thus there was no choice of law or jurisdictional issue to argue about.

Second, Schedin was not very sick when he was prescribed Levaquin, Goldser said. In giving him the drug, the doctor "used a sledgehammer to kill an ant," he said. That, Goldser said, was important for two reasons: It showed that the drug was "overpromoted," and it allowed the plaintiffs to avoid the issue about what a great drug Levaquin was for treating serious illness, since Schedin didn't have a serious illness.

Goldser said he does not think the verdict is attributable to juror antipathy toward Big Pharma. Five potential jurors were disqualified because they said in voir dire that they didn't like drug companies, Goldser said. "The sitting jurors had no negative thoughts" about pharmaceutical companies, he said. "I was nervous about the jury to begin with."

Goldser pointed out that when the news of the verdict broke, it garnered a predictable number of online comments about runaway juries and the McDonald's coffee case. Four jurors responded and defended the verdict, writing that they had heard the evidence and the people commenting had not, he said.

There was a little scare toward the end of the trial when the jury sent a note that it was unable to reach a verdict on punitive damages. Apparently what was happening in the jury room was that a juror had vacation plans and wanted to leave.

But the jury did keep deliberating and reached a verdict in a couple of hours, after the juror evidently changed his plans, Goldser said. The juror's request to leave might seem unusual to some, Goldser said, but the court wanted to accommodate the juror if possible. "When you have a jury pressured, it creates uncertainty about the verdict," he said. "We want them to feel good about the verdict."

A victory for MDL

Besides being a win for an 82-year-old man and for other plaintiffs who have claims concerning the drug Levaquin, the outcome of Schedin v. Johnson & Johnson is a victory for the multidistrict litigation process, Ronald Goldser, the plaintiff's attorney, said.

The purpose of MDL is to coordinate cases for discovery and possibly to result in earlier resolution of cases, but not everybody likes it. Some criticize the MDL emphasis on discovery and not on getting a case to trial.

"I am particularly happy the MDL process worked," Goldser said. "It's sometimes seen as a black hole

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[for cases]," he said.

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