

Actos trial set for Md.

In first case to go to jury, Calif. judge set aside April verdict of \$6.5 million

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Jury selection is scheduled to begin Tuesday in a Baltimore family's \$10 million wrongful death lawsuit against the maker of the prescription diabetes medication Actos.

Diep An's widow and three children allege An died because Takeda Pharmaceuticals U.S.A. Inc. and its affiliates did not meet its legal duty to warn doctors and patients that long-term use of the drug could cause bladder cancer.

Diep An, who began taking Actos in 2007 for type 2 diabetes, died on Jan. 14, 2012.

Takeda denies the family's allegations and said it plans to mount a strong defense of Actos during what attorneys expect will be a four-week jury trial before Judge M. Brooke Murdock in Baltimore City Circuit Court.

Last April, in the first Actos trial to go to verdict, a California state jury awarded the plaintiffs \$6.5 million. However, the judge in the case threw out the verdict in May, ruling there was insufficient evidence to link plaintiff Jack Cooper's bladder cancer to his use of Takeda's drug.

The Deerfield, Ill.-based company is also fighting similar claims elsewhere, including more than a thousand in actions that were filed in federal courts nationwide and consolidated in the U.S. District Court in western Louisiana.

"Takeda is confident in the therapeutic benefits of Actos and its importance as a treatment for type 2 diabetes," Kenneth D. Greisman, Takeda Pharmaceuticals U.S.A. Inc.'s general counsel, said in a statement.

"We have empathy for the plaintiff, but Takeda believes that we acted responsibly with regard to Actos," Greisman added. "Patient safety is a critical priority for Takeda and we intend to vigorously defend Takeda against these lawsuits."

Failure to warn claim

Actos has had a checkered history.

The federal Food and Drug Administration approved the drug in 1999 to treat type 2 diabetes, and it became the diabetes drug of choice in 2007 after GlaxoSmithKline's Avandia was linked to a higher risk of heart attack.

However, the FDA released a safety advisory on June 15, 2011, stating that using Actos for more than one year "may be associated with an increased risk of bladder cancer." That same month, Germany and France suspended distribution of the drug due to its suspected link to bladder cancer.

In its lawsuit, the An family claims that Takeda knew of the drug's risks before it was prescribed to Diep but did not warn him or his doctors.

The Takeda companies "concealed and continued to conceal their knowledge of Actos' unreasonably dangerous risks from Diep An, his physicians,

other consumers and the medical community," the complaint states.

"Specifically, defendants failed to adequately inform consumers and the prescribing community about the risk of bladder cancer associated with the use of Actos," the lawsuit adds. "Diep and his physicians would not have used Actos had defendants properly disclosed the risks associated with its long-term use."

The family's failure to warn claim is one of several related allegations it makes against Takeda. The lawsuit also alleges design and manufacturing defects in the drug, as well as breaches of express and implied warranties of safety by the company.

Stuart Simms, an attorney for the family, declined to comment on the coming trial beyond citing the papers filed with the court since the initial filing on June 8, 2012.

"From all parties and all sides it would be inappropriate to comment prior to commencement" of the trial, said Simms, of **Brown Goldstein Levy LLP**.

The Baltimore law firm is serving as co-counsel in the case, which was filed by attorney Michael J. Miller of The Miller Firm LLC in Orange, Va. The firm was also on Cooper's legal team in the California litigation.

The An family's claim is one of at least three similar lawsuits that have been filed against Takeda in state and federal courts in Maryland.

On March 2, 2012, the estate and family of John Dunlavey Sr. filed suit

in Baltimore City Circuit Court.

Dunlavey, a type 2 diabetic, began taking Actos in 2006, was diagnosed with bladder cancer in January 2009 and died March 15, 2009, according to the lawsuit, which was also filed by Miller. The case was removed to the U.S. District Court in Baltimore on April 19, 2012, on the company's motion.

The estate and son of Myrtle Hunt filed suit in the U.S. District Court in Baltimore on April 9, 2012. Hunt, a type 2 diabetic who died of bladder cancer on Sept. 12, 2009, had taken

Actos for approximately two years, according to the lawsuit filed by attorney Austin B. Kirk, of Saiontz & Kirk P.A. in Baltimore.

In spring 2012, U.S. District Judges Benson E. Legg and Richard D. Bennett transferred the Dunlavey and Hunt cases, respectively, to the federal court in Lafayette, La., which was chosen to handle the Actos cases under the federal multi-district litigation statute.

That law permits — but does not require — federal-court litigation with a common defendant and common

questions of fact to be transferred to a single court.

The first trial in the multi-district litigation is expected to start next January.

Bruce R. Parker, Takeda's attorney, did not return telephone and email messages seeking comment on the case and why he did not move to have the An family's case heard in federal court. Parker is with Venable LLP in Baltimore.

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