

LOUISIANA**FEATURED VERDICT****MEDICAL****DRUGS & SUPPLEMENTS**

Failure to Warn — Breach of Warranty

Cancer developed because of diabetes medication: plaintiff**VERDICT** **\$9,001,475,000****CASE** Terrence Allen and Susan Allen v. Takeda Pharmaceuticals International, Inc., Takeda Pharmaceuticals U.S.A., Inc. (f/k/a Takeda Pharmaceuticals North America, Inc.), Takeda Pharmaceutical Company, Limited, Takeda Pharmaceuticals LLC, Takeda Global Research and Development Center, Inc., Takeda California, Inc. (f/k/a Takeda San Diego Inc.) and Eli Lilly and Company, No. 11-cv-00643**COURT** U.S. District Court, Western District, Lafayette, LA**JUDGE** Rebecca Doherty**DATE** 4/8/2014**PLAINTIFF****ATTORNEY(S)** Richard J. Arsenault (co-lead), Neblett, Beard & Arsenault, Alexandria, LA
Paul J. Pennock (co-lead), Weitz & Luxenberg, P.C., New York, NY
Mark Lanier, The Lanier Law Firm, P.C., Houston, TX**DEFENSE****ATTORNEY(S)** Sara J. Gourley, Sidley Austin LLP, Chicago, IL
John E. McElligott, Davidson, Meaux, Sonnier & McElligott, Lafayette, LA
Bruce R. Parker, Venable LLP, Baltimore, MD**PLAINTIFF****EXPERT(S)** Kristin K. Kucsma, M.A., economics, Livingston, NJ

Dan M. Bagwell, B.S.N., R.N., life care planning, San Antonio, TX

Scott E. Delacroix, Jr., M.D., urology, Metairie, LA
David A. Kessler, M.D., public health, San Francisco, CA
David Madigan, Ph.D., biostatistics, New York, NY
Sebastian Schneeweiss, M.D., Sc.D., epidemiology, Boston, MAKristin Kucsma
Chief Economist
Sobel Tinari Economics Group**DEFENSE
EXPERT(S)**Paolo Boffeta, M.D., M.P.H., epidemiology, New York, NY
Lewis A. Chodosh, M.D., biology, Philadelphia, PA
Samuel M. Cohen, M.D., Ph.D., pathology, Omaha, NE
Michael Droller, M.D., urology, New York, NY
David W. Feigel, Jr., M.D., M.P.H., fda new drug review/approval procedures, Santa Rosa Valley, CA
Jeffrey M. Peters, Ph.D., molecular pathology, University Park, PA**FACTS & ALLEGATIONS** Beginning in June 2006, plaintiff Terrence Allen, 56, from Batavia, N.Y., began being prescribed pioglitazone hydrochloride, known by the brand name Actos, for treatment of symptoms related to diabetes mellitus. In January 2011, Allen was diagnosed with bladder cancer.

Allen, along with his wife, Susan, sued the manufacturer and seller of Actos, Takeda Pharmaceuticals International

Inc., alleging products liability and breach of implied warranty. They also sued five other Takeda entities; the six entities stipulated that, for purposes of trial, they would be treated as one entity, "Takeda." The couple also sued the company that helped promote Actos to doctors in the United States, Eli Lilly and Company.

The lawsuit was initially filed in the United States District Court for the Western District of New York. It was transferred to United States District Court for the Western District of Louisiana, where the trial took place. The case was the bellwether in the Actos Multi-District Litigation.

The plaintiffs alleged that the Actos Allen was taking was a substantial contributing factor to the development of his bladder cancer. The Allens alleged that the defendants were negligent in their failure to warn doctors about the possibility of the drug's bladder cancer risk. They alleged that warnings on the product's packaging were insufficient, and did not adequately warn doctors about the risk of bladder cancer associated with the drug. Allen, who went off the medication three months after he was diagnosed, testified that had he been warned of the possible side effects, he would not have consented to taking the drug.

The Allens also alleged that the marketing of Actos on the part of Takeda and Eli Lilly was negligent. They also alleged that Takeda breached the warranty. They contended that Takeda allowed Actos to be sold with the implication that it was safe for use for its intended purpose. They claimed that the drug was represented as not having a high amount of life-threatening side effects.

Defense counsel argued that Actos was not a defective product, and that the label adequately warned of the risk of bladder cancer associated with taking the drug. Even the development of bladder cancer by users of the drug did not constitute breach of warranty, as Actos was "minimally safe," they argued.

INJURIES/DAMAGES *cancer; loss of consortium; nausea; tumor*

As a result of the development of his bladder cancer, a tumor developed in Allen's bladder. He underwent a surgical removal of the tumor. He followed up with treatment for his bladder, including a three-year course of BCG treatments.

Allen claimed that as a result his cancer, he continues to suffer from pain, nausea, loss of appetite, and feelings of despair and embarrassment. He claimed that he remained at risk for the return of the cancer, and has to undergo regular cystoscopies to determine if the tumor has experienced any re-growth.

In addition to a recovery for compensatory damages of medical expenses and pain and suffering, Allen sought a recovery for punitive damages. The jury was not asked for any specific amounts.

Susan Allen sought a recovery for her derivative claims, seeking damages for past and future loss of consortium as a result of her husband's cancer.

RESULT The found that Takeda and Eli Lilly were negligent in their failure to warn Allen about the risks of the development of bladder cancer associated with Actos. They also found that the defendants negligently marketed the product and breached the warranty. It determined that the Allens' damages totaled \$1,475,000 in compensatory damages and \$9 billion in punitive damages, for a total award of \$9,001,475,000. The punitive damages were split between the defendants, with \$6 billion assessed against Takeda and \$3 billion against Eli Lilly. The jury allocated 75 percent liability to Takeda and 25 percent to Eli Lilly.

SUSAN

ALLEN \$75,000 past lost of consortium
\$250,000 future lost of consortium
\$325,000

TERRENCE

ALLEN \$75,000 past medical cost
\$500,000 future medical cost
\$75,000 past pain and suffering
\$500,000 future pain and suffering
\$9,000,000,000 punitive damages
\$9,001,150,000

TRIAL DETAILS Trial Length: 11 weeks
Trial Deliberations: 2 hours
Jury Composition: 2 male, 6 female

EDITOR'S NOTE This report is based on information that was provided by plaintiffs' counsel. Defense counsel did not respond to the reporter's phone calls.

—Kirk Maltais

