VERDICTSEARCH

An ALM Publication

Products Liability

Vol. 7 Issue 9 | March 2010

VERDICT of the MONTH

Medical

Years of hormone therapy led to cancer, plaintiff claimed

$34,300,000

Kendall v. Wyeth Pharmaceuticals Inc.

Philadelphia Co., Pa., Ct. C.P.

Plaintiff Counsel Tobias L. Millrood, Pogust Braslow & Millrood LLC, Conshohocken, Pa.

Defense Counsel Charles P. Goodell Jr., Goodell, DeVries, Leech & Dann, LLP, Baltimore; Michael T. Scott, Reed Smith LLP, Philadelphia

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CASES of NOTE

Santos sued Crown Equipment Corp. for products liability. He claimed that the forklift was defectively designed and that the defect caused his injury. The Crown forklift was manufactured with an open operator compartment for ingress and egress. Santos contended that the truck should have been equipped with a door that completely enclosed the operator compartment. He alleged that such a door would have prevented his injury.

According to the plaintiff's engineering experts, very few, if any, serious lower leg injuries were seen with trucks in the forklift industry that had doors enclosing their operator compartments. They claimed that the forklifts with doors were safer than those without doors.

Crown Equipment's design expert and former safety director testified that placing a door on a stand-up forklift truck to totally enclose the operator compartment would create an unsafe environment for forklift operators involved in other types of accidents. The expert claimed that Crown Equipment chose not to install operator compartment doors because other types of dangerous and potentially fatal accidents were just as prevalent as the type of accident experienced by Santos.

The defendant's statistical analysis expert testified that the 30-year accident history of the forklift model at issue indicated that that the product was safe for its intended purpose. He testified that forklifts with operator compartment doors made up less than 1 percent of the forklift population. The fact that very few injuries had occurred with such a small number of trucks was not indicative that a truck with a door was safer. He opined that the incident rate of lower leg injuries in trucks without doors was more than reasonable considering all industrial accidents.

INJURIES/DAMAGES *amputation, above-the-knee; comminuted fracture; fracture, fibula; fracture, tibia*

Santos sustained comminuted fractures to his left tibia and fibula. Loss of vascular integrity led to an above-the-knee amputation of Santos' leg several days later. Santos' wife, Beatrice Santos, claimed loss of consortium.

RESULT The jury rendered a defense verdict.

DEMAND	$10,000,000
PLAINTIFF EXPERT(S)	**Thomas A. Berry, P.E.**, mechanical, Wichita, KS **David Falk**, prosthetics, Delray Beach, FL **Craig H. Lichtblau, M.D.**, physical medicine, Palm Beach, FL **Richard Ziernicki, Ph.D.**, design, Centennial, CO
DEFENSE EXPERT(S)	**Dan Dunlap, P.E.**, design, **Larentius Marais**, statistical analysis, Stanford, CA **Thomas M. McNish, M.D.**, biomechanics of injury, San Antonio, TX

EDITOR'S NOTE This report is based on information provided by defense counsel. Plaintiffs' counsel did not respond to the reporter's phone calls.

–Shannon Green

VERDICT *of the* MONTH

MEDICAL

DRUGS & SUPPLEMENTS

Failure to Warn

Years of hormone therapy led to cancer, plaintiff claimed

VERDICT	**$34,300,000**
CASE	Donna Kendall v. Wyeth Pharmaceuticals Inc., Wyeth Inc. and Pharmacia & Upjohn Co. Inc., No. 040600965
COURT	Philadelphia County Court of Common Pleas, PA
JUDGE	Victor J. DiNubile Jr.
DATE	11/23/2009
PLAINTIFF ATTORNEY(S)	**Tobias L. Millrood** (lead), Pogust Braslow & Millrood LLC, Conshohocken, PA **Zoe Littlepage**, Littlepage Booth, Houston, TX **Ronald Rosenkranz**, Finkelstein & Partners, LLP, Newburgh, NY
DEFENSE ATTORNEY(S)	**Charles P. Goodell Jr.** (lead), Goodell, DeVries, Leech & Dann, LLP, Baltimore, MD (Pharmacia & Upjohn Co. Inc.) **Michael T. Scott** (lead), Reed Smith LLP, Philadelphia, PA (Wyeth Inc., Wyeth Pharmaceuticals Inc.) **Barbara R. Binis**, Reed Smith LLP, Philadelphia, PA (Wyeth Inc., Wyeth Pharmaceuticals Inc.) **Gita F. Rothschild**, McCarter & English, LLP, Newark, NJ (Pharmacia & Upjohn Co. Inc.)

MEDICAL

FACTS & ALLEGATIONS From October 1991 to the end of 1997, plaintiff Donna Kendall, 59, a grocery store clerk from Decatur, Ill., took estrogen-based Premarin, manufactured by Wyeth Pharmaceuticals Inc. of Collegeville, Pa., in tandem with progestin-laden Provera, made by Pharmacia & Upjohn Co., which later became a division of Pfizer Inc., to treat menopausal syndrome at the recommendation of her physician. The prescribing physician suggested that the combination of estrogen and progestin would be good for her cardiovascular health, good for her bone health and could be taken long term. In 1998, at the advice of her physician, Kendall was switched to the single-pill combination of estrogen and progestin, Prempro, which was made by Wyeth. She took it through October 2002 until she detected a lump in her left breast. On Nov. 12, a biopsy confirmed that the lump was invasive ductal breast cancer.

Kendall, claiming that her cancer resulted from her 11 years of combination hormone therapy, sued Wyeth and Upjohn, asserting that defendants failed to adequately test the drugs when they were aware they could potentially cause cancer, and that their conduct was willful and wanton. Since Kendall was an Illinois resident, the defendants asked for a choice of law analysis and motion was granted for Illinois law to apply. Plaintiff's counsel presented letters dating back to 1976 from the Food and Drug Administration and independent researchers, as well as internal documentation from the defendants' own scientists, urging the drug makers to conduct studies for cancer risks of the estrogen- and progestin-based drugs. Counsel contended that had the defendants started their respective cancer studies on the drug in the early 1980s — assuming that it would take a year to 1.5 years to start the study and about four years to administer it — researchers would have discovered the harmful effects of the combination of estrogen and progestin (Premarin plus Provera; or Prempro) by 1990 or earlier. Kendall began taking the combination therapy in 1991. Therefore, Kendall would not have developed breast cancer.

The plaintiff's theory that the companies did not adequately warn of breast cancer risk focused on the defendants' active steps to neutralize and discredit researchers. Counsel presented evidence attempting to show that the drug companies spent tremendous amounts of money making sure that the medical data outlining the cancerous effects of combination hormone therapy would not get through to physicians. To do this, the defendants hired a public relations firm to devise media plans in attempt to counter any perceived ill publicity about the drugs, which was done to protect sales and profits, according to plaintiff's counsel.

The plaintiff's pharmaceutical regulatory experts testified that the defendants were aware of a need to conduct a cancer study in response to the hormone drugs but failed to adequately do so. The experts also testified that the warnings on the Premarin, Provera and Prempro drug labels failed to adequately cite the risks of developing breast cancer.

The defendants denied the allegations. According to the defense, doctors have been prescribing hormone-therapy medicines for the treatment of menopausal symptoms-hot flashes and night sweats - as well as for the prevention of post-menopausal osteoporosis, for decades. The FDA has said that hormone therapy "is the most effective FDA-approved medicine for relief of hot flashes, night sweats or vaginal dryness," cited the defense. Counsel maintained that the FDA regularly and thoroughly reviewed the benefits and risks of these medicines, and has consistently determined that the benefits outweigh the risks for the appropriate woman. Additionally, hormone-therapy medicines are among the most thoroughly studied drugs. The defendants claimed they conducted or supported more than 180 studies covering 180,000 women that examined the risks and benefits of hormone therapy. The defense asserted that 19 of these studies expressly examined hormone therapy and breast cancer risk, the first of which was published in 1959. These studies were published in peer-reviewed medical journals and were consistent with the then-current medical science. Counsel argued that the Women's Health Initiative, the most definitive study on hormone therapy and breast cancer, reaffirmed the increased relative risk of breast cancer that was already in the labeling for Prempro in 1995.

According to the defense experts, the labels for Premarin and Prempro, which are the official, FDA-approved descriptions of their benefits and risks relied upon by doctors, are and have been accurate and science-based, and have warned of the risk of breast cancer for many years. Breast cancer risks were discussed at least nine times in the 1995 launch label for Prempro, and have been included in the Premarin label for decades. The defense experts testified that the FDA acknowledged that the pre-Women's Heath Initiative labels reflected "what was known at the time about benefits and risks" of these medicines. And after the Women's Health Initiative, the FDA required new class labels based in large part on what Wyeth had done months before.

The defense presented evidence that showed that Kendall's doctor was warned about the risk of breast cancer, and that he conveyed this risk to the plaintiff before she used the medication. The defense relied upon her doctor's videotaped deposition in which he acknowledged that he was aware of the risk of breast cancer associated with hormone therapy, and that he informed Kendall of this risk prior to the time when she began taking the medication.

INJURIES/DAMAGES *cancer, breast; emotional distress; mastectomy; nausea; scar and/or disfigurement, breast*

After her cancer diagnosis, Kendall underwent a left mastectomy. Doctors then discovered that the cancer spread to five lymph nodes in her left axilla which prompted aggressive chemotherapy and radiation treatment through summer 2003, and then treatment of anti-estrogen drug Arimidex, which the plaintiff will take indefinitely. In December 2003, due to her 50 to 75 percent recurrence rate, she had a right mastectomy in conjunction with left-sided reconstruction (at that time Kendall's left nipple was removed); however, due to the inability to cosmetically repair the site, the plaintiff had to return in May 2004 to complete the revisions.

Kendall sought approximately $200,000 for past medical bills and an unspecified amount of damages for future medical costs, which included Arimidex treatment and yearly examinations.

The plaintiff's epidemiologist expert opined that the combination of hormone-replacement therapy can cause breast cancer. The plaintiff's breast surgeon expert gave a differential diagnosis, saying that Kendall's cancer was caused by the combination of Premarin, Provera and Prempro.

Kendall talked about her experience battling cancer; how she lost her hair and fingernails and how she tried to make herself vomit — but couldn't — to alleviate the constant feeling of nausea. She said that she is reminded of her disfigurement and deformity every day, yet she continues to remain positive and hopeful through her faith and support of her family. The plaintiff recounted a story during her chemotherapy when she saw a bulletin board at the hospital that advertised a support group for women managing cancer and surviving. Kendall said that, had she seen that advertisement before she had cancer, it would not have meant anything to her. Having seen it while treating the cancer, it was relevant and made an impact. Kendall sought damages for past and future pain and suffering and emotional distress.

The defense epidemiologist expert said that medicine is unable to identify what causes breast cancer. Therefore, it is inappropriate for the plaintiff to say that it was the defendants' drugs that caused her cancer, since the therapy only has a small increased risk of cancer.

The defense OB-GYN expert testified that the benefits of combination hormone therapy outweigh the risks, which was evidenced by the fact that Prempro is still used by millions of women today.

RESULT The jury found that the defendants failed to adequately warn the plaintiff's physician of the extent of the risk of breast cancer, and that their negligence was a substantial factor in bringing about the breast cancer. Wyeth was found 60 percent negligent and Upjohn 40 percent negligent. In the bifurcated punitive-damages phase, the jury found that the defendants' conduct was of such a degree as to constitute malice or a willful or wanton disregard of the rights of others. Kendall was awarded $34.3 million.

DONNA KENDALL

$6,300,000 compensatory damages
$16,000,000 punitives against Wyeth
$12,000,000 punitives against Upjohn
$34,300,000

TRIAL DETAILS

Trial Length: 28 days
Trial Deliberations: 9 hours
Jury Vote: 10-2 compensatory damages; 12-0 punitive damages
Jury Composition: 6 male, 6 female

PLAINTIFF EXPERT(S)

Donald Austin, M.D., epidemiology (cancer), Portland, OR
Cheryl D. Blume, Ph.D, drug development, Tampa, FL
Elizabeth Naftalis, M.D., breast surgery, Dallas, TX
Suzanne Parisian, M.D., FDA new drug review/approval procedures, Phoenix, AZ

DEFENSE EXPERT(S)

Brian S. Englander, M.D., radiology, Philadelphia, PA
Roy A. Jensen, M.D., pathology, Kansas City, KS
Heidi Jolson, M.D., FDA new drug review/approval procedures, Bethesda, MD
Paul Pharoah, M.D., epidemiology (cancer),
Valerie Montgomery Rice, M.D., OB-GYN, Nashville, TN

EDITOR'S NOTE This report is based on information that was provided by plaintiff's and defense counsel.

–Aaron Jenkins