VERDICTSEARCH

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VERDICT of the MONTH

Medical

Mastectomy result of drug's failure to warn, plaintiff claimed

$78,746,345

Barton v. Wyeth Pharmaceuticals

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

Plaintiff Counsel Zoe Littlepage and Rainey C. Booth, Littlepage Booth, Houston

Defense Counsel George E. McDavid, Reed Smith LLP, Princeton, N.J.

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CASES of NOTE

MEDICAL

VERDICT of the MONTH

DRUGS & SUPPLEMENTS

Failure to Warn

Mastectomy result of drug's failure to warn, plaintiff claimed

VERDICT **$78,746,345**

CASE Connie Barton v. Wyeth Pharmaceuticals Inc., Wyeth-Ayerst Pharmaceuticals Inc., Wyeth-Ayerst International Inc., Wyeth Laboratories Inc. and Wyeth Pharmaceuticals, No. 040406301

COURT Philadelphia County Court of Common Pleas, PA

JUDGE Norman Ackerman

DATE 10/26/2009

PLAINTIFF ATTORNEY(S) Zoe Littlepage (co-lead), Littlepage Booth, Houston, TX
Rainey C. Booth (co-lead), Littlepage Booth, Houston, TX
Samuel Abloeser, Williams Cuker Berezofsky, Philadelphia, PA

DEFENSE ATTORNEY(S) **George E. McDavid** (lead), Reed Smith LLP, Princeton, NJ
Lauren E. Handler, Porzio, Bromberg & Newman, P.C., Morristown, NJ
Matthew V. Johnson, Williams & Connolly LLP, Washington, DC

FACTS & ALLEGATIONS In May 1997, plaintiff Connie Barton, 52, an administrative assistant, began treating with daily hormone-replacement therapy Prempro, the estrogen-progestin drug manufactured by Wyeth Pharmaceuticals Inc., of Collegeville, Pa., which was prescribed by her physician to treat her menopausal hot flashes. Barton also took the drug because, according to her doctor, it was cardio-protective and prevented Alzheimer's disease. In May 2002, Barton was diagnosed with cancer in the left breast after a mass was detected during a routine mammogram.

Barton, claiming that her cancer resulted from her five years of hormone-replacement therapy, sued Wyeth, asserting that the defendant failed to adequately warn doctors and consumers of the associated risks of breast cancer with Prempro, and that the drug maker's conduct was willful and wanton.

Since Barton was an Illinois resident, Wyeth asked for a choice of law analysis and motion was granted for Illinois law to apply.

Plaintiff's counsel argued that Wyeth was negligent for its failure to accompany the drug's daily dial pack with any warnings about the risk of developing breast cancer from hormone-drug treatment and breast cancer. According to the plaintiffs' epidemiology expert, the years when prescriptions of the estrogen-plus progestin drug Prempro were up, so too were hormone-positive breast cancer cases; and when the prescriptions were down, so were the cancer rates. Based on the scientific trends, the Wyeth-manufactured menopause drugs directly caused the plaintiffs' hormone-positive breast cancers, testified the expert.

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 a generic progestin; or Prempro) by 1990 or earlier. Barton began taking the combination therapy in 1997. Therefore, Barton would not have developed breast cancer.

The plaintiffs' pharmaceuticals regulatory expert testified that Wyeth was aware of a need to conduct a cancer study in response to the hormone drugs but failed to adequately do so, and said that the warnings on the Prempro drug labels failed to adequately cite the risks of developing breast cancer.

In his videotaped deposition, Barton's physician said that he prescribed Prempro because he thought it would treat his patient's hot flashes as well as benefit her heart, bones and brain. He said that at the time he thought breast cancer was theoretical, though a possibility, as medical studies did not show much of an increased risk of cancer. Plus, Barton had no family history of the disease.

Wyeth denied the allegations. Defense counsel argued that the warnings on the Prempro labels were adequate and provided notice for physicians which, in turn, warned patients.

Wyeth argued that FDA-approved hormone therapy (HT) medicines are important treatment options for certain post-menopausal women. Doctors have been prescribing HT medicines for the treatment of menopausal symptoms (hot flashes and night sweats), as well as for the prevention of post-menopausal osteoporosis, for decades, according to the defense. The FDA has said that HT "is the most effective FDA-approved medicine for relief of hot flashes, night sweats or vaginal dryness." The FDA has 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, defense counsel argued.

Defense counsel argued that Wyeth has acted responsibly by studying its hormone therapy medicines closely, including the risk of breast cancer, for decades. HT medicines are among the most thoroughly studied drugs. Wyeth conducted or supported more than 180 studies covering 180,000 women that examined the risks and benefits of HT (including the WHI). Nineteen 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. The most definitive study on hormone therapy and breast cancer, the Women's Health Initiative, reaffirmed the increased relative risk of breast cancer that was already in the labeling for Prempro in 1995, defense counsel argued.

Defense counsel argued that 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.

Defense counsel argued that guidance to use Premarin and Prempro at the lowest dose and for the shortest duration needed to meet treatment goals has been included in the labels of these medicines for decades. 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 label and the Physicians' Desk Reference in which it is included carry the most authoritative information on a medicine's risks and benefits. The FDA has acknowledged that the pre-Women's Health 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, defense counsel argued.

In Barton's case, an expert on mammography reviewed her breast X-rays and testified that she had cancer before she started taking Prempro, and that she had three important risk factors for breast cancer in addition to taking HT medicines. These were her age, having dense breasts and having abnormalities in her breast tissue, defense counsel argued.

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

Following her diagnosis, Barton underwent a modified left mastectomy and reconstructive surgery in June. She was subsequently put on Arimidex and Tamoxifen, which she continued taking together through 2005. Past and future medical expenses were stipulated at $3.74 million.

The plaintiff's mammography expert compared Barton's films pre-Prempro to her films while on the drug and opined that her breast density was more while on Prempro. The breast surgery expert said that Barton, who had no family history of cancer, had a 10 percent reoccurrence rate.

Barton recounted the humiliation she felt after the removal of her breast and the fear of dying. She sought damages for past and future pain and suffering, disfigurement and emotional distress.

The defense argued that Barton had signs of breast cancer before she went on hormone-replacement therapy.

RESULT The jury found that Barton's ingestion of Prempro was a proximate cause in bringing about her injury, and that she sustained a 10 percent likelihood of future reoccurrence of breast cancer. Jurors also found that Wyeth negligently failed to adequately warn Barton's physician about Prempro; that the defendant's negligent failure to adequately warn was a proximate cause of the plaintiff's physician's conduct in prescribing Prempro to her; and that Wyeth's conduct was willful and wanton. Barton was awarded $78,746,344.97.

CONNIE BARTON	$75,000,000 punitive damages $96,345 economic damages $3,500,000 noneconomic damages $150,000 recurrence without reduction for the probability of reoccurrence $78,746,345
TRIAL DETAILS	Trial Length: 29 days Jury Vote: 11-1 on punitive damages
PLAINTIFF EXPERT(S)	**Donald Austin, M.D.**, epidemiology (cancer), Portland, OR **Cheryl Blume, Ph.D.**, pharmaceuticals regulatory affairs, Tampa, FL **Graham Colditz, M.D.**, epidemiology (cancer), Cambridge, MA **Matthew Hollon, M.D.**, medical/health, Seattle, WA **Elizabeth Naftalis, M.D.**, breast surgery, Dallas, TX **Randall M. Patten, M.D.**, mammography, Olympia, WA
DEFENSE EXPERT(S)	**Susan Allen, M.D.**, preventive medicine, Washington, DC **Jacqueline Gutmann, M.D.**, ob-gyn -- see also gynecology, Philadelphia, PA **Elizabeth Ann Rafferty, M.D.**, radiology, Boston, MA

POST-TRIAL The defense filed motions for a new trial and JNOV.

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

–Aaron Jenkins