

Associated Press

Boston lawsuit claims DES-breast cancer link

By DENISE LAVOIE, AP Legal Affairs Writer – January 8, 2012

BOSTON (AP) — Arline MacCormack first heard about DES from her mother when she was 17.

Three decades later, MacCormack believes that the drug her mother took to prevent miscarriages caused her to develop breast cancer at age 44.

MacCormack, of Newton, is one of 53 women from around the country who are suing drug companies who made and promoted DES for millions of pregnant women from about 1938 to the early 1970s. In 1971, the U.S. Food and Drug Administration told doctors to stop prescribing DES for their pregnant patients after a study found that taking DES during pregnancy appeared to increase the risk of developing a rare vaginal cancer years later for DES daughters in their teens and 20s.

DES, or diethylstilbestrol (dahy-eth-uhl-stil-bes'-trawl), is a synthetic estrogen that was prescribed to millions of women in the United States, Europe and other countries to prevent miscarriages, premature birth and other problems.

The case in Boston is being closely watched by DES daughters around the country.

Thousands of lawsuits have been filed since the 1970s alleging links between DES and cervical and vaginal cancer, as well as infertility problems. Many of those cases were settled before trial. The Boston case is believed to be the first major litigation alleging a link between DES and breast cancer in DES daughters over the age of 40.

MacCormack, now 50, said she was stunned when she was diagnosed with breast cancer six years ago after having mammograms every six months since she turned 40 because she had had several benign cysts removed over the years.

"The characteristics of my cancer were for women over 60 typically. It wasn't the type of cancer a 40-year-old or a 44-year-old woman gets," said MacCormack.

"When I read the research that's been done, I found I had more chance of getting it because my mom took DES," she said.

The women's lawyers say their case is supported by a recent study that suggests that breast cancer risk is nearly doubled in DES daughters over the age of 40. The average woman has about a 1 in 50 chance of developing breast cancer by 55. The study, led by Dr. Robert Hoover, a researcher at the National Cancer Institute, found that the chance for DES daughters is 1 in 25.

The lawsuit alleges that 14 drug manufacturers — including Eli Lilly and Co. and Bristol-Myers Squibb Co.— withheld from doctors and the FDA reports that showed DES did not prevent miscarriages and raised serious questions about the safety of the drug.

"This drug, DES, was the biggest human experiment of quackery in the history of medicine," said Aaron Levine, a Washington, D.C., lawyer who filed the Boston lawsuit and represents another 18 DES daughters making similar claims.

Representatives and lawyers for Eli Lilly and Bristol-Myers Squibb declined to comment on the lawsuit.

In court and in public documents, the companies argue that a firm link between DES and breast cancer has not been established and that the DES daughters who are suing them have not shown that DES caused their cancers.

"We believe these claims are without merit and are prepared to defend against them vigorously," Eli Lilly said in its most recent annual report.

The drug companies also argue that the medical community does not generally accept that fetal exposure to DES causes breast cancer.

"There is not a single published study, a respected medical treatise or textbook, nor a pronouncement by one of the prominent societies dedicated to the discovery of cancer causes which claims a causal link between prenatal DES exposure and breast cancer has been proven," Bristol-Myers Squibb argued in a motion to exclude the testimony of the plaintiffs' experts.

U.S. Magistrate Judge Marianne Bowler has heard testimony from a dozen experts on both sides during a hearing on the drug companies' motions, which argue that the opinions of the women's experts are not based on reliable science.

If Bowler grants the drug companies' motion, the case will not go to trial, Levine said. But if she allows the plaintiffs' experts to testify, the case can proceed to trial.

Final arguments on the motion are scheduled for Jan. 19 in U.S. District Court.

DES was prescribed at a time when medical advice was rarely questioned and drugs were not subjected to the kinds of rigorous clinical trials they are today, said Dr. Michael Grodin, a professor of medical ethics at Boston University's School of Public Health. Grodin said proving a link between DES and the plaintiffs' breast cancer could be difficult.

"There's an issue of causation, but even if it did cause the cancer, that doesn't mean there was negligence," Grodin said.

"The question of negligence is what did they know, when did they know it and what did they do about it? Those are all in contention," he said.

Jackie White, 48, of Centerburg, Ohio, a plaintiff in the lawsuit, was diagnosed with breast cancer in 2010 at age 47. Tests showed 20 tumors in one breast and two pre-cancerous lumps in the other. The cancer had also spread to her lymph nodes. She had a double mastectomy, and did six months of chemotherapy and seven weeks of radiation. White said her mother, a nurse, told her at age 13 that she had taken DES while pregnant, prompting White to get regular gynecological exams and mammograms over the years. She said she has no family history of breast cancer.

White said it wasn't until she saw high estrogen levels in her pathology reports that she began to wonder whether DES could have caused her cancer.

"I exercise daily. I ate healthy, low-fat, did all of the maintenance screenings that a person needs — self-exams, mammograms, OB-GYN appointments — eliminated the exposure to birth control or things like that, just like doctors recommended," she said.

"I'm not any of the things that are the highest-known reasons for risk factors for breast cancer."

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