

Federal Judge Sets Trial Dates for Two Hormone Replacement Therapy Cases in Arkansas – Thousands More Pending

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United States District Judge William Wilson in Little Rock, Arkansas, has tentatively set the trial dates for two cases against Pfizer and Wyeth alleging the hormone replacement therapy (HRT) medications they manufactured and marketed caused the female plaintiffs to develop breast cancer. These two lawsuits were selected from some 3,500 now pending in the Little Rock area. HRT had been suspected of increasing the risk of a number of serious medical problems, including heart disease and invasive breast cancer for some time. It was only after the National Institutes of Health ended a study on combination HRT three years earlier than planned in July 2002, because of concern over these risks, that thousands of lawsuits were filed against the various manufacturers of HRT drugs.

In July 2005, after years of research, analysis, and debate, the International Agency for Research on Cancer, the U.N.'s cancer research agency, has reclassified HRT from "possibly carcinogenic" to "carcinogenic." The panel of 21 scientists concluded that the evidence from several recent studies was consistent and reliable enough to link HRT to breast cancer thereby fully justifying the reclassification. The normal risk of a woman (not on HRT) developing breast cancer is slightly more than 14%. Long-term use of HRT raises that risk to almost 17%.

The panel also concluded that HRT slightly increases the risk of endometrial cancer when progestin is taken fewer than 10 times per month. HRT has been a long-standing and widely accepted treatment for women experiencing some of the more uncomfortable effects of menopause. In the past few years, however, this popular therapy has come under fire as a result of evidence linking HRT to many serious health risks.

A number of studies suggest that women undergoing HRT are exposing themselves to long-term harm that far outweighs the severity of the symptoms being treated.

For some women, HRT might consist of an estrogen-only treatment while others are given a combination of estrogen and progestin. This latter option is slightly less common but is still a popular solution to menopausal discomfort. Both types of HRT are used by an estimated 13.5 million women in the United States alone.

HRT has been around since the early 1940s when women began taking high doses of estrogen to counteract many of the temporary, but recurring, discomforts of menopause. In the 1970s, however, it was discovered that this particular form of estrogen therapy created an unacceptably high risk of uterine cancer. This prompted the trend by doctors to prescribe progestin along with significantly lower doses of estrogen.

Recent studies now show that there are too many health risks associated with HRT to justify its being used automatically as a “cookie cutter” treatment of choice or as if it were a woman’s only available option.

Women are now being advised to work closely with their doctor to customize any HRT plan so as to take only the minimum dosage necessary.

Prempro and Premarin are the two major HRT drugs. Both are manufactured by Wyeth Pharmaceuticals. Prempro is a combination estrogen-progestin treatment and Premarin is an estrogen-only treatment. There are approximately 6 million women taking Prempro and 11 million women taking Premarin. In 2003, the two drugs had combined sales of \$2.1 billion.

Although Premarin, the first HRT drug, was introduced in 1942 for the purpose of alleviating symptoms of menopause such as hot flashes and vaginal dryness, a study in the Journal of American Medical Association (“JAMA”) has linked it to ovarian cancer.

Prempro, on the other hand, has been linked to various serious side effects including dementia, Alzheimer’s disease, stroke, blood clots, pulmonary embolisms, lupus, heart attack, and breast cancer.

Women taking Prempro have a 29% higher risk of heart attack, a 41% higher risk of stroke, and a 26% higher risk of breast cancer. Those figures alone should prompt women to consult their physicians regarding alternative treatments or methods of treatment. This is especially so for women who experience only minor symptoms of menopause such as vaginal dryness which respond to alternative treatments such as creams and vitamin E.

The most important thing stressed by researchers and medical professionals alike is that Prempro, Premarin and other HRT drugs should be taken in the smallest dosages (that produce effective results) for the shortest duration as possible.

In addition, women who are only experiencing minor symptoms of menopause might want to forego HRT therapy altogether.

Finally, even women seeking relief from more severe symptoms should do their own benefit/risk analysis by asking questions, reading available reports, and keeping in mind the potential risks associated with HRT.

HRT medications can double the risk of vascular dementia and Alzheimer's disease, especially in women over 65. Short rather than long-term use is recommended in order to avoid this unwanted side-effect.

This information was first made public in an issue of the Journal of American Medicine released in May of 2003.

Another study published at the same time revealed that, in addition to the increased risk of dementia, HRT may have harmful effects on the general cognitive function of older women leading to mild memory loss amongst other things.

Combination therapy consisting of estrogen and progestin, such as Prempro, has now been linked to an increased heart attack risk of up to 81% in the first year of treatment.

One possibility for this newly discovered heart attack risk is that HRT might cause more rapid clotting and therefore, a woman with one or more narrowed blood vessels would be at risk if there was a sudden clotting of the blood in those constricted areas.

While it was previously believed that combination estrogen-progestin drugs could actually prevent heart attack, a recent study found that hormones do not slow the clogging of arteries. In fact, all women who take hormones appear to be at a higher risk for heart attack.

The Women's Health Initiative ("WHI"), a federally sponsored organization, conducted a study to determine the risks associated with HRT. (The study was actually abruptly aborted in 2002 as too many women were being put in harm's way and experiencing a variety of severe side-effects such as heart disease, stroke, blood clots, and breast cancer.)

Estrogen-progestin pills such as Prempro are now being linked to an aggressive form of breast cancer. The WHI study was responsible for discovering crucial information regarding this dangerous risk.

Of the 16,608 women in the study ranging from ages 50-79, breast cancer developed in 245 women who used estrogen-progestin pills and 185 women in the placebo group.

Collectively, the women on hormones had larger tumors which began to spread to nearby tissue and distant parts of the body in about 25% of hormone users with cancer as opposed to only 16% of the women with cancer in the placebo group. Tumors may also grow at a faster rate in women taking hormones.

A similar longitudinal study conducted in Britain concluded that women who were receiving HRT had a greater risk of developing breast cancer in comparison to women not receiving therapy. The study involved 1 million women between the ages of 50 and 64.

Those who took the hormones demonstrated a 66% greater risk of developing breast cancer and a 22% greater risk of dying from it within 6 years. Women who took estrogen alone had only a 30% increased risk of developing breast cancer leading some experts to conclude that the original (estrogen only) option is a safer one despite the fact that it, too, has been shown to increase the risk of breast cancer.

The researchers determined that, over a decade, HRT would be responsible for 10,000 extra cases of breast cancer in England and an extra 100,000 cases in the United States among menopausal women ages 50-64.

Yet another study conducted in Sweden concluded that women who were receiving HRT were more prone to new and recurring cancer. This study was also stopped due to the unacceptably dangerous risks posed to the 345 women participating in the study.

Perhaps the most dangerous risk regarding HRT and breast cancer is the newfound risk of inaccurate and abnormal mammograms.

Out of the estimated 3 million women on HRT in the United States, about 120,000, or 4%, could experience abnormal mammograms related to the HRT. Combined HRT, such as Prempro, causes the breast tissue to increase in density thereby making it more difficult to obtain a clear and accurate mammogram. In cases where there is a delay in detecting the cancer treatment, options are more limited and the prognosis is less favorable.

In an editorial from the Feinberg School of Medicine at Northwestern University, Peter H. Gann and Monica Morrow summed up this disturbing finding by stating: **“The ability of combined hormone therapy to decrease**

mammographic sensitivity creates an almost unique situation in which an agent increases the risk of developing a disease while simultaneously delaying its detection.”

Note: Ovarian and uterine cancers have also been linked to HRT even though it was previously thought that hormones would help to prevent the onset of such cancers.

The two Arkansas actions were selected as “bellwether cases” and have been scheduled for trial on July 31 and October 10.

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