Plaintiffs Attempt to Revive Hormone Therapy Mass Tort

The Legal Intelligencer
By Amaris Elliott-Engel
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Howard Bashman

In one of the first Philadelphia hormone replacement therapy mass tort cases to reach appellate review, a three-judge Superior Court panel heard arguments Tuesday that a trial judge shouldn't have tossed the plaintiff's lawsuit out of court because the suit was filed within two years of the publication of a widely publicized study linking hormone drugs with an increased risk of breast cancer.

Judges Mary Jane Bowes, Christine L. Donohue and Joan Orie Melvin heard oral arguments in *Simon v. Wyeth Pharmaceuticals* in the Superior Court's Philadelphia courtroom. *Simon* is one of the bellwether cases that was selected to be tried first in the Complex Litigation Center's hormone replacement therapy, or HRT, program.

The *Simon* case is one of about 1,500 HRT cases filed in the Philadelphia courts.

Several other Philadelphia HRT cases that are on appeal from summary judgments based on statute of limitations questions have been consolidated before the Superior Court and are now in a briefing schedule.

One main question before the court is whether plaintiffs Merle Simon, a New Jersey woman who was diagnosed with breast cancer May 21, 2002, and Stephen A. Simon, Merle Simon's husband, filed a timely lawsuit alleging the manufacturers of Simon's hormone replacement therapy drugs are liable for her breast cancer. The Simons filed the lawsuit two years after Simon's diagnosis with breast cancer but within two years of the release of the National Institutes of Health's Women's Health Initiative, or WHI, study, which found that the use of hormone drugs estrogen and progestin increase the risk of breast cancer, according to appellate briefs.

Another main question before the court is whether Philadelphia Common Pleas Judge Nitza Quiñones Alejandro appropriately granted judgment notwithstanding the verdict on the issue of proximate causation. Quiñones Alejandro found that Simon's gynecologists continued to prescribe to other patients the same HRT drugs Simon alleges caused her cancer after the release of the WHI study, according to appellate briefs.

Quiñones Alejandro also granted JNOV on the statue of limitations questions because she found that Simon reasonably should have known that one of her HRT drugs was a cause of her cancer and that her statue of limitations expired two years after her breast cancer diagnosis, according to appellate briefs.

Simon was prescribed Provera, a manufactured form of progestin, which is manufactured by Upjohn Company, and Premarin, a form of estrogen manufactured by Wyeth, from 1992 to 1996, according to appellate briefs. In 1996, Simon was then prescribed Prempro, a Wyeth product that combined estrogen and progestin in one, until her breast cancer diagnosis, the appellate briefs said.

A Common Pleas jury found in its May 15, 2007, verdict that Upjohn's Provera drug was a cause of Simon's breast cancer; that Upjohn failed to warn adequately of the risk of breast cancer from consuming Provera, a synthetic progestin; and that the Simons' lawsuit was timely under the discovery rule because Merle Simon first learned that her usage of Provera could be linked to her breast cancer because of the July 9, 2002, publication of the WHI government-funded, randomized study, according to appellate briefs. The jury awarded $1.5 million compensatory damages.

The jury found against Stephen Simon's loss of consortium claim, and the jury found that Wyeth had adequately warned Merle Simon in its product information about the risk of breast cancer from HRT drugs, according to appellate briefs.

Howard J. Bashman, a Willow Grove, Pa., solo practitioner, argued on behalf of the Simons. William Hoffman of Kaye Scholer in Washington, D.C., argued on behalf of Upjohn.

If Simon had called the federal Food and Drug Administration regulatory agency right after her diagnosis but before the release of the WHI study to ask if her HRT drugs had caused her breast cancer, Bashman said during oral argument, "What that person would have told her is the current state of knowledge is uncertain."

It was only until 49 days after Simon's cancer diagnosis when the WHI study was publicized that it was reasonable for Simon to have realized Upjohn's medication could have caused her breast cancer, the appellants' brief said.

In his appellate brief, Bashman wrote: "The trial court's entry of j.n.o.v. fails to view the evidence in the light most favorable to Mrs. Simon, impermissibly substitutes the trial judge's view of the evidence for the jury's view of the evidence, and therefore must be reversed."

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Upjohn argues Simon's claims are barred by the statute of limitations and not rescued by the discovery rule because a reasonable person would have asked about the relationship between the HRT regimen and the breast cancer diagnosis, including the fact that Simon's HRT was stopped after her cancer diagnosis, according to Upjohn's brief.

Donohue asked Bashman why Simon's statue of limitations wasn't triggered when she read the informational inserts included with her HRT drugs.

Bashman said that Upjohn's product information included no warning about breast cancer and Wyeth's product information said it was unknown if breast cancer was caused by HRT.

Bashman said the state Supreme Court's decision last week in *Wilson v. El-Daief* reserves consideration of the application of the discovery rule to juries and doesn't require plaintiffs to know more than their doctors.

Bowes pointed out to Hoffman that, under the *Wilson* case, plaintiffs do not need to know more than doctors.

Hoffman, however, said that, while the *Wilson* plaintiff asked her doctor about what was wrong with her for 13 months, Simon didn't ask her doctors about what caused her breast cancer and she had two years after her diagnosis to explore the cause of her cancer and her legal options.

While "we're all sympathetic to the shock" of being diagnosed with breast cancer, Hoffman said, "the statute and public policy ... gives you two years to figure that all out."

When Donohue asked about the importance of the WHI study over previously available scientific information about a HRT-breast cancer link, Hoffman cited the summary judgment decision made by Judge Allan L. Tereshko in *Coleman v. Wyeth* , one of the several summary judgment decisions consolidated for appeal.

Hoffman noted that Tereshko found that before the release of the WHI study there was plentiful public information, including news reports by journalists Peter Jennings and Tom Brokaw, to indicate that scientific studies were finding a link between HRT drugs and an increased risk of breast cancer.

When Bowes asked about the fact the WHI study made a stronger case for a HRT-breast cancer link, Hoffman said that the only difference between previous epidemiological studies and the WHI study was that WHI was a placebo-controlled trial.

On the proximate cause issue, Bashman told the judges in oral argument that affirming Quiñones Alejandro's ruling in this area would prevent Upjohn from ever being liable in these types of cases.

All a plaintiff must demonstrate to establish proximate cause in failure-to-warn cases is that an adequate warning would have prevented the doctor from prescribing the medication to the plaintiff, according to the Simons' brief.

Hoffman said in oral argument that Simon hasn't been able to demonstrate proximate cause because Simon's doctors still prescribe the same HRT drugs to other patients and there is no evidence in the record that her doctors relied on allegedly inadequate warning labels in making decisions about prescribing Upjohn's Provera drug.

The Simons' trial counsel are James A. Morris Jr. and Brian D. Ketterer of Brent Coon & Associates.

Upjohn's counsel also includes Wendy Dowse, Steven Glickstein and Maris Veidemanis of Kaye Scholer and Emily J. Lawrence and James D. Pagliaro of Morgan Lewis & Bockius. •