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IN FEN-PHEN TRIAL, THE UNINJURED SUE FOR PREVENTIVE MAINTENANCE

Matt Ackermann

Unlike conventional class actions, the plaintiffs in the fen-phen diet drug suit that went to trial last Wednesday in Middlesex County haven't suffered illness or injury. In fact, their class is specifically defined to exclude people who've suffered illness or injury.

"We are not here for money; we are here for monitoring," said plaintiff's lead counsel Esther Berezofsky, a partner with Cherry Hill's Williams & Cuker, during opening arguments. "Early intervention is important. If people can get treatment, people can get help."

No one would argue with that premise. The question is whether someone with no discernible injury from a product has a cause of action, based solely on the possibility that an injury may become manifest in the future.

The suit, *Vadino v. American Home Products*, MID-L-425-98MT, seeks echocardiographic testing of the 94,400 New Jersey residents who took the diet drugs for more than three weeks before they were taken off the market in September 1997.

By some estimates, it would cost \$1,000 a year to monitor each user, which comes to \$944 million over the 10 years of monitoring anticipated.

That dwarfs the \$23 million a Texas jury awarded on Aug. 6 to a woman who alleged actual harm from the drugs. Worse for the manufacturers, it puts them on the hook for both the monitoring costs and any injuries that the monitoring discloses.

"Certainly drug companies are looking at an increased liability," says Armand Leone Jr., a Glen Rock product liability attorney who is also a medical doctor. "Look at it practically, instead of being liable for the one in 20,000 that gets sick, drug companies could be liable for the other 19,999."

So instead of the 4,000 suits now faced by American Home Products, one of the manufacturers, the company could be liable for medically monitoring the estimated 1 million people who took the drug nationally --whether they have developed heart and lung problems or not. Cost: \$10 billion.

Other New Jersey suits have won medical monitoring funds. One of the largest came in a hazardous contamination suit before Superior Court Judge Marina Corodemus, who is also the judge in the fen-phen case. In July 1997, 427 Pompton Lakes residents received \$250,000 in monitoring funds as part of a \$38.5 million settlement in *Armona v. E.I. du Pont de Nemours & Co.*, MID-L-122-93.

But unlike the plaintiffs in the Armona case, the fen-phen plaintiffs are

currently asymptomatic.

Fen-phen, a combination of drugs that tricks the brain into believing that the stomach feels full, was marketed under the brand names Redux and Pondimin until 1997, when Pondimin -- or fenfluramine -- was taken off the market after a study linked it to heart-valve damage in some patients.

The Middlesex County suit was filed by three named plaintiffs: Lynn Vadino, 35, of Washington Township; Karol DeBardinis, 33, of Bellmawr; and Deneen Giantonno, 35. The women lost weight while using a combination of the drugs, but also experienced symptoms such as shortness of breath after taking the pills, according to the suit.

Berezofsky's co-counsel, Sol Weiss, a partner with Philadelphia's Anapol, Schwartz, Weiss, Cohan, Feldman and Smalley, said in opening arguments that American Home Products, which made Pondimin, enjoyed healthy sales while withholding information from consumers about its potentially deadly side effects.

"I suggest to you that's the 'why' for not being honest with the Food and Drug Administration, not telling the doctors, and not telling you," Weiss told the six women and four men on the Middlesex jury Wednesday.

Berezofsky held up a Barbie doll in court as she accused American Home Products of promoting its diet drug by using the social pressure placed on women to look thin.

When his turn came, American Home Products' attorney Peter Bleakley countered that the diet pills were intended to "jump-start a lifestyle change" for obese people and, in those cases, the benefits outweighed the risks.

Bleakley, a partner at Washington, D.C.'s Arnold & Porter, said that the risk of developing primary pulmonary hypertension affects only one in every 20,000 fen-phen users. He said, "the risks of [primary pulmonary hypertension] were always very, very small and even those very small risks don't apply to the people in this case."

Bleakley noted that symptoms of primary pulmonary hypertension are usually detected within a year of the problem developing. Since the drug has been off the market for two years and none of the plaintiffs have developed any symptoms, they are in the clear, he says.

However, James Pettit, a partner with Cherry Hill's Greitzer & Locks and another of the two dozen plaintiffs' attorneys involved in the class action, argued in his opening statement that symptoms of primary pulmonary hypertension have developed as many as six years after a person has stopped taking fen-phen.

The trial continues today with the plaintiff's first expert, Dr. Harris Busch, a pharmacology professor at Houston's Baylor University, on the stand. Busch also testified against American Home Products last month in the Texas case. The plaintiffs will also call Dr. Mark Detsch, the company's medical affairs director, to testify next week.

Ex-Smokers the Next Class?

So if asymptomatic diet-drug users can get the right to free health monitoring, why not tobacco users?

"Due to Judge Corodemus' decision to allow for this case to be brought as a class action, we are planning to create a class action on behalf of asymptomatic smokers," says Terry Bottinelli, a partner with Hackensack's Herten Burstein Sheridan Cevasco Bottinelli & Litt. "Tobacco use causes emphysema, cancers and chronic pulmonary diseases. Early detection will help save lives." Bottinelli says he'll file a class-action suit seeking medical monitoring and cessation programs for New Jersey's 1.75 million smokers.

But it will be an uphill battle. In November, a week before the state Attorney General's Office accepted the tobacco settlement, a Third U.S. Circuit Court of Appeals panel dismissed a class-action medical monitoring suit brought on behalf of 2 million Pennsylvania smokers. In *Barnes v. The American Tobacco Co.*, 97-1844, the court held the case could not proceed as a class action because it entailed too many issues relating to whether each smoker was addicted to nicotine.

Says lawyer-cum-doctor Leone: "If that class is going to get certified, their attorney is going to need to have a group of people that have already stopped smoking. It is going to be hard to get a medical monitoring fund if you are still puffing on a cigarette."

Bottinelli's 11th-hour attempt to join another suit, *Cosentino v. Philip Morris Inc.*, MID-L-5135-97, New Jersey's \$7.6 billion share of the national tobacco settlement, was rejected last year by Superior Court Judge Jack Lintner.