

Lawsuit questions drug's need

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October 9, 2005

Nancy Yost doesn't have a heart condition, but every day for the past eight years, she has dutifully taken Lipitor to rein in her LDL cholesterol, which can get as high as 340.

Now Yost, a 73-year-old retiree in Brooklyn Heights, wonders whether taking the medicine has been worthwhile. She's a plaintiff in a class-action lawsuit that charges Lipitor manufacturer Pfizer aggressively promoted the drug to patients like herself - even though, the suit says, there is no proof statins prevent heart attacks in women and seniors who aren't already suffering from heart disease or diabetes.

"Lipitor is one of the most widely prescribed drugs in the world, and millions of women and elderly are taking it. But there's no clinical proof it has ever benefited women or the elderly," said Steve Berman, managing partner of Hagens Berman Sobol Shapiro and the lead attorney in the case.

"We believe Pfizer intentionally ignored the scientific evidence - and lack thereof - and launched a multimillion-dollar ad campaign designed to push the drug to anyone they could convince to buy it."

A Pfizer spokeswoman, Vanessa Aristide, declined to comment on the lawsuit, filed late last month in U.S. District Court in Boston. The lawsuit seeks to reimburse consumers and health insurers for the costs of the medication. Annual sales of Lipitor are \$10 billion, and the lawsuit claims 74 percent of patients taking it don't need it.

The lawsuit follows a wide-reaching campaign in recent years to raise awareness among women that they are at risk for heart disease, especially if they have diabetes, and that they need to watch their "bad" LDL cholesterol and blood pressure, lose weight, quit smoking, exercise and eat right. Pfizer has been one of the major sponsors of the American Heart Association's campaign, Go Red For Women.

The class-action lawsuit doesn't seek to undermine the heart disease message, and it doesn't deny that Lipitor reduces LDL cholesterol in women. But the ultimate goal of statin therapy is to prevent heart attacks, strokes and deaths, and the lawsuit says clinical trials have not proven the drugs do that for women and seniors who are free of heart disease and diabetes.

In fact, in one large clinical trial that included 2,000 women, the women who took Lipitor developed 10 percent more heart attacks and heart disease deaths than women who took the dummy pill, the suit says.

Another trial of 5,804 patients aged 70 to 82 who took statins - cholesterol-lowering drugs - found no reduced risk of heart disease for those who didn't already have a heart condition, but an increased risk of cancer.

"Cholesterol in and of itself isn't harmful; it's an integral part of the normal function of our body," said Dr. John Abramson, a physician and author of the book "Overdosed America," who is an expert consultant to the plaintiffs' attorneys.

He emphasized that the only reason to treat LDL cholesterol is "if treatment reduces the risk of heart disease and cardiovascular disease."

The distinction isn't always made. Responding to questions about the lawsuit and cholesterol-lowering drugs for women, officials of the American Heart Association pointed to a fact sheet that says simply, "High cholesterol and heart disease can be just as deadly for women as men."

Dr. Nieca Goldberg, a spokeswoman for the American Heart Association and a specialist in women's heart disease, emphasized that patients need to be evaluated individually and not be treated unless necessary. Still, her concern is that many women are still undertreated for heart conditions and risk factors.

"We know cholesterol is a risk factor for heart disease. ... And many women at high risk for cardiovascular disease still don't get adequate cholesterol lowering," she said.

"I would agree that if somebody has just an LDL of 140 and no other risk factors, they should try changes in diet and exercise before you start them on medication."

In her own practice, Goldberg said, she adheres to guidelines developed by the National Cholesterol Education Program, which recommend cholesterol-lowering drugs for women and older people, even if they do not have a history of heart disease. The updated guidelines last year called for more aggressive use of statin drugs.

The class-action lawsuit against Pfizer implicitly challenges the education program guidelines for disease-free women and elderly, noting that one section of the guidelines even acknowledges that clinical trials of cholesterol lowering in women in this category are "generally ... lacking." Goldberg said more clinical trials including large numbers of women are needed.

So what should people 65 and older do about high LDL cholesterol? Experts say lifestyle changes can make an enormous difference.

"Exercising and eating a Mediterranean-style diet will improve your chances of staying healthy, regardless of your cholesterol," Abramson said.

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