Investigating Fen-Phen

Fen-Phen was supposed to be a diet drug miracle. And during its heyday in the mid-'90s, the drug did help many thousands of Americans lose weight. But Fen-Phen, which is actually a combination of two drugs, fenfluramine and phentermine, had another effect. It had the potential to damage the hearts of those who took it.

Researchers found that fenfluramine can in some cases lead to pulmonary hypertension, a rare, almost always fatal, disease. It was also linked to another potentially fatal disorder, heart valve malfunction, in which the blood isn't pumped properly.

In response to this danger, fenfluramine was pulled from the market in late 1997. But by this point, according to some medical experts, hundreds of thousands of people may have suffered some type of permanent but not necessarily life-threatening damage to their hearts.

Now, a 60 Minutes II investigation with U.S. News & World Report has revealed that Wyeth-Ayerst, the maker of fenfluramine, knew more than it told about the pulmonary hypertension risks.

Thousands of people who took Fen-Phen are now suing the company. Lawyers representing these people say that Wyeth-Ayerst put the profits of the company over the safety of the patient.

The company was also in the process of developing another form of the drug, known as Redux. But a vocal minority within the Food and Drug Administration had some of the same concerns about Redux as it had for fenfluramine.

Texan Kip Petroff is one of the lawyers representing victims of pulmonary hypertension.

"They knew that they had far more cases of pulmonary hypertension and
deaths associated with that than they told doctors about," Petroff says. "They didn't report it to doctors at all."

Instead, they sent an eight-page letter pointing out that they met all their FDA reporting requirements and insisting that they took prompt action when necessary. They also pointed out that pulmonary hypertension was a well-understood danger with diet drugs, and their products had been approved by the FDA. When we asked the FDA why it approved these drugs, no one there would talk with 60 Minutes II on camera. Wyeth also argues that new studies have shown that the connection between heart valve problems and its drugs has been overstated.

In 1996, the Mayo Clinic began a study of Fen-Phen and discovered 24 cases of heart valve damage. It released the report in August 1997, and just a few weeks later the company withdrew both Redux and Pondimin from the market.

Wyeth's medical director, Dr. Marc Deitch, said in an interview when the drugs were pulled that the heart valve problem was new to them. "This is the first time this kind of information has been received by us," says Deitch. "We were quite surprised."

But, say lawyers involved in the lawsuits against Wyeth, the company should have examined this problem earlier.

Lawyer Aaron Levine, who settled a case with Wyeth says this was another problem the company should have examined.

Says Levine: "We have 100 reports which in one way or another talk about valve damage, and no one followed it up. No one called these people. No one called their doctors. No one said, 'Let's do an echocardiogram on them.' And that was more than negligent."

The company says neither it, the FDA nor foreign drug regulators saw an "association between the drug and heart valve disease." They all thought the heart valve problems were caused by another disease or drug.

The first Fen-Phen trial against Wyeth Ayerst is due to start next month.