FDA Doc Claims Fen-Phen Cover-Up

The drug company that manufactured "fen-phen," a diet medication linked to heart ailments, covered up problems with the drug that emerged during Food and Drug Administration testing, a former FDA scientist tells CBS News.

Fen-phen was removed from the market in 1997. Thousands of people who took the drug have sued American Home Products of Madison, N.J., for health problems they claim the drug caused.

In an Eye on America investigation, CBS News Correspondent Sharyl Attkisson reports the FDA's key reviewer of fen-phen, Dr. Leo Lutwak, claims the company knew about the problems long before the drug was pulled.

"I felt from the very beginning the drug companies were covering up. I felt from the very beginning that these drugs were dangerous," said Lutwak.

He claims American Home Products twisted the meaning of his research to make it seem as if there was no way to predict fen-phen's hazards.

"What I had actually written was, that in view of the covering up of information by the drug company, the FDA had no way of predicting some of these side effects," he said.

One of those who sued American Home Products was Patricia Buol, who developed severe heart problems after taking fen-phen. She's now in line for a life saving heart-lung transplant.

The company settled with Buol this week. "Being part of my kids' lives and doing their everyday activities is a struggle," said Buol. "But I just take one day at a time and do the best I can."

Dr. Lutwak's testimony is crucial to fen-phen cases like Buol's. But the FDA won't let him testify. Now Lutwak says he's planning to retire, making him free to testify at will.
"I followed the rules and regulations, I didn't go public. I tried to work within the system, it didn't work. People died as a result of a dangerous deadly drug being released," he said.

Defendant American Home Products would not be interviewed, but has said in the past it "acted responsibly and lawfully.

FDA Commissioner Jane Henney refused a CBS News request to answer the allegations.

The agency's last commissioner, Dr. David Kessler, criticized the agency's current approach to drug regulation.

"I have some concerns that we may be losing sight of what the FDA is all about," said Kessler. "The question is, who's the agency's customers? Who's the agency partner?"

Consumer advocates say the FDA is constantly keeping damaging information from the public.

"They view the drug industry in many ways as their customers, at least the bosses do, as opposed to viewing the public as the customers they need to protect from some of the excesses of the drug industry," said Sidney Wolfe of Public Citizen.

Concerns about the FDA also emerged during the controversy over the diabetes drug Rezulin.

Kessler said the agency needs to realize the American consumer is its customer.

American Home Products also makes such drugs as Caordarone, Sectral, Protonix, Synvisc and Pnu-Imune.

Fen-phen is actually a combination of two drugs, fenfluramine and phentermine, which work by suppressing the appetite of a person who is trying to lose weight.

It was estimated that in 1996, 18 million Americans took the drugs.

But a report in the August 1997 New England Journal of Medicinefound that fenfluramine can in some cases lead to pulmonary hypertension, a rare, almost always fatal, disease. It was also linked to heart valve malfunction.
In September, 1997, the FDA, saying it was "acting on new evidence about significant side-effects," asked the manufacturers to voluntarily withdraw both medications, marketed under the names Pondimin (fen-phen), and Redux, a similar medication.

Wyeth-Ayerst Laboratories, a subsidiary of American Home Products, complied.

However, the company continued to deny the drugs caused the alleged problems. In November, 1998, Wyeth-Ayerst published a study that compared heart function in people who had taken fen-phen and a group who hadn't, and concluded there was no significant differences in cardiovascular clinical outcomes."

But that didn't stop the fen-phen fallout.

A February, 1999 60 Minutes II investigation with U.S. News & World Report revealed that Wyeth-Ayerst knew more than it told about the pulmonary hypertension risks, a charge the company denied.

In September 1999, the Wall Street Journal reported that the FBI was investigating the FDA's approval of Redux.

A month later, American Home Products agreed to pay up to $4.83 billion to settle the more than 11,000 fen-phen lawsuits, one of the biggest product liability settlements ever.

As part of the settlement agreement, the company admitted no wrongdoing.