

# Popular diet pill may cause heart problems

By DANIEL Q. HANEY  
AP Medical Editor

BOSTON — Fifty-eight more cases of heart valve damage among users of fen-phen have been reported to the U.S. Food and Drug Administration since new concerns arose last month about the popular prescription pill combination taken by millions to lose weight.

As a result, the agency said yesterday it will require new drug labels warning patients of the potential danger.

And a drug company announced a new study on the medication's effects.

The possibility that the diet drugs might damage heart valves came to light July 8, when doctors from the Mayo Clinic said they had identified 24 cases.

The FDA then asked physicians to report any other patients and that search turned up the 58 addi-

tional cases, all but two of them in women.

How many of those cases were actually caused by the medicines, however, is unclear.

Some doctors wondered whether newly vigilant physicians might be hearing heart murmurs — the tell-tale sound of bad valves — that have been there all along.

Fen-phen is a combination of the prescription drugs fenfluramine and phentermine that suppresses appetite.

Both drugs are approved by the FDA for short-term use in dieting, although not specifically in combination.

"We are not absolutely saying you shouldn't use them," said Dr. James Bilstad, a drug evaluation chief at the FDA.

"But physicians and patients need to consider the risk very carefully before going on them," he said.

Given the large number of people using these drugs, the risk of heart damage is clearly low.

But just how great the risk is — even whether it truly exists — cannot be determined without a careful study comparing diet pill users with overweight people who are not taking the medicines.

Drug company officials have raised the possibility that obesity itself — not drugs to treat the condition — may actually be causing the heart problems.

To help settle these questions, Wyeth-Ayerst Laboratories, which makes the Pondimin brand of fenfluramine, said yesterday it will sponsor a study of 1,200 fen-phen users and others being treated for obesity at several institutions.

"Recognizing that both drugs have been available for many years and millions of patients have taken them, we were quite surprised to have this finding," said Dr. Marc

W. Deitch. "But we take it very seriously," said Deitch, Wyeth-Ayerst's medical director.

The FDA described its latest findings in last Thursday's issue of the New England Journal of Medicine.

Fenfluramine is chemically similar to Redux, another popular appetite suppressant that came on the market last year.

The FDA said it had also learned of four cases of heart valve damage in Redux users.

There also were two in patients taking fenfluramine alone and two in patients taking Redux plus phentermine.

At Interneuron Pharmaceuticals, which makes Redux, spokesman Bill Boni said:

"This is a very limited number of cases that may or may not have anything to do with the drug and may be related to the underlying condition of obesity."

Dr. Michael Hamilton, an obesity expert at Duke University, said he discovered a heart murmur in one of his own fen-phen patients.

He discovered the murmur in his patient after the Mayo Clinic cases were reported, he said.

"I don't know if it was always there, whether I hadn't listened carefully enough that first day, whether the air conditioner noise made it difficult to hear," he said.

Doctors appear to have cut back their use of all three drugs.

Figures from IMS America, a drug market research company, show that in the month after the Mayo Clinic findings were made public, new prescriptions for fenfluramine fell 40 percent.

Redux fell 23 percent and phentermine fell 18 percent.

The valve damage appears to be separate from another well-known hazard of diet drugs — an often

fatal condition called pulmonary hypertension, a narrowing or blockage of the artery that carries blood from the heart to the lungs.

It can result in permanent damage to both the lungs and the heart muscle.

The drugs suppress appetite by boosting serotonin — a chemical that relays messages in the brain.

A review in last Wednesday's issue of the Journal of the American Medical Association said heavy doses of both Redux and fenfluramine appear to disrupt brain levels of serotonin in animals.

There is no evidence of this in people.

Manufacturers recommend that the diet drugs be used only by seriously obese people.

Obesity contributes to breathing problems, diabetes, heart disease, high blood pressure, stroke, gallstones and arthritis and plays a part in 300,000 deaths a year.

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