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Phen-Fen and Heart Valve Disease

In July, 1997, researchers at the Mayo Clinic reported a case series of 24 women who developed an unusual form of disease of the heart valves. All 24 women were using the combination of fenfluramine and phentermine.

The disease primarily affected the left side of the heart, and five patients required valve replacement. In cases where samples of valve tissue were obtained, there was an unusual appearance of the heart valves generally only seen with a serotonin-producing tumor called carcinoid or with excessive amounts of medications containing ergot.

Following these initial case reports, the Food and Drug Administration (FDA) has continued to receive a number of reports of similar valve disease from physicians. Some of these cases involved patients who were taking fenfluramine or dexfenfluramine alone. No cases were reported in patients taking phentermine alone. In addition, physicians at five sites provided information to the FDA regarding patients, most of whom did not have signs or symptoms of valve disease. About 30% of patients at these sites showed some evidence of damaged valves, usually mild or moderate. While this was not a controlled study, and further studies are needed to determine how common the problem is in treated patients compared to the general population of overweight people, the findings were of enough concern to prompt the FDA to ask the manufacturers of fenfluramine and dexfenfluramine to voluntarily recall the drugs.

This withdrawal took place on September 15th 1997. Patients who were on fenfluramine or dexfenfluramine have been advised to discontinue the drug, and to contact their physicians for an evaluation to look for signs and symptoms of heart disease and to determine the need for an echocardiogram. For more information about the withdrawal of fenfluramine and dexfenfluramine, you can access the FDA website on Questions and Answers about Withdrawal of Fenfluramine (Pondimin) and Dexfenfluramine (Redux) at <http://www.fda.gov/cder/news/fenphenqa2.htm>. Two small studies looking at relationships between sibutramine and valvular heart disease did not find any increase in valve lesions in patients taking sibutramine compared with placebo.