

Cholesterol drug linked to 31 deaths

Although numerous reports have shown that high cholesterol can usually be lowered through proper diet, medical doctors around the country are prescribing drugs for patients with this problem. Among the most popular has been Baycol (cerivastatin), manufactured by Bayer Pharmaceutical Division.

Now, however, Baycol has been linked to rhabdomyolysis, a severe muscle adverse reaction which has caused 31 deaths so far.

Baycol is a member of a class of cholesterol-lowering drugs that are commonly referred to as "statins." Statins lower cholesterol levels by blocking a specific enzyme in the body that is involved in the synthesis of cholesterol.

Even though it is well known that all statins have been associated with this disease, the FDA approved the drug in 1997.

According to the consumer advocacy group, Public Citizen, statins have been responsible for 50 other deaths in the U.S. and should carry a stronger warning label. In response, a spokeswoman for Bristol-Myers Squibb, which markets the statin Pravachol, said only "Our drug is very safe." She did not explain how a "safe drug" could cause the deaths of 50 people.

The FDA said it has no intentions of reviewing the statins, which have become huge money makers for the drug industry.

Rhabdomyolysis is a condition that results in muscle cell breakdown and release of the contents of muscle cells into the bloodstream. Symptoms of rhabdomyolysis include muscle pain, weakness, tenderness, malaise, fever, dark urine, nausea, and vomiting. The pain may involve specific groups of muscles or may be generalized throughout the body.

Most frequently the involved muscle groups are the calves and lower back; however, some patients report no symptoms of muscle injury. In rare cases the muscle injury is so severe that patients develop renal failure and other organ failure, which can be fatal.

After receiving reports of the 31 deaths, the drug company "voluntarily" withdrew Baycol from the market.

SOURCES: "Bayer Voluntarily Recalls Baycol," FDA Talk Paper, Aug. 8, 2001.