# Bayer AG Pulls Cholesterol Drug Baycol

*Reuters* news service reports on August 8, 2001 that German drug company Bayer AG has taken its controversial cholesterol drug Baycol off the market after 31 people taking the drug died from a rare muscle-cell disorder.

The FDA reports that it agreed with the decision. Baycol (chemical name cerivastatin), is in a class of cholesterol drugs called statins, and was approved for use by the FDA in the United States in 1997.

The muscle-cell disorder is called rhabdomyolysis and causes muscle-cell breakdown, muscle pain, weakness, tenderness, malaise, fever, dark urine, nausea and vomiting. In extreme cases rhabdomyolysis is so severe that patients can develop kidney and other organ failure leading to death.

In a related story on August 20, 2001, Reuters Health news service reported that the Washington DC-based consumer advocacy group Public Citizen has filed a petition with the FDA urging them to require a 'black box warning' on all statin drugs. 'Black box warnings' are the strongest labeling caution the FDA can require.

The statin drugs that Public Citizen wants labeled are Pravachol (pravastatin), Lipitor (atorvastatin), Lescol (fluvastatin), Mevacor (lovastatin) and Zocor (simvastatin).

Oddly after Bayer pulled Baycol, the FDA suggested that doctors switch their patients to these other statin drugs, but they have also been associated with hundreds of recent reports of rhabdomyolysis as well. 772 cases of rhabdomyolysis associated with all of the statins were reported between October 1997 and December 2000, accounting for a total of 81 deaths.

By way of commentary, we seriously question the wisdom of the FDA who first approves the drug, then agrees that it needs to be taken off the market, then tells doctors to substitute other drugs for the drug that was taken off the market with ones that are similar but are causing the same type of problems that gave reason for the original drug to be withdrawn in the first place. Does any of this make any sense to anyone?

# Cholesterol Statin Drugs May Cause Birth Defects

The April 8, 2004 issue of the New England Journal of Medicine reports that pregnant women who take the cholesterol-lowering drugs known as statins stand a much higher risk of having babies born with birth defects.

Researchers from the United States National Institutes of Health discovered that exposing babies to statins in the first trimester of pregnancy is associated with limb deformities and severe central nervous system defects.

The researchers point out that other studies have shown that "these are the kinds of problems that occur if the embryo does not get enough cholesterol in early pregnancy to develop normally."

The Food and Drug Administration (FDA) requires warning labels on the drugs advising against taking them during pregnancy.

The problem lies in the fact that many pregnancies are not planned and women continue to take the drugs unaware they are exposing their babies to danger.

In this study, 20 out of 52 babies exposed to statins in the womb were born with birth defects.

# Cholesterol Drug Crestor May Damage Kidneys

Reuters reports on October 29, 2004 that the U.S consumer group Public Citizen has called for a ban on the anti-cholesterol statin drug Crestor after 29 patients who took it have developed kidney damage.

According to Public Citizen's analysis, there are 6.4 reports of kidney damage or failure for every 1 million Crestor prescriptions filled. Public Citizen figures this to be about 75 times higher than all the anti-cholesterol statin drugs combined.

Dr. Sidney Wolfe, head of Public Citizen's Health Research Group told the Food and Drug Administration that "it becomes clearer by the day that this drug is uniquely toxic without offering any unique benefit, and that it must be removed from the market."

Public Citizen points out that anti-cholesterol statin drugs have come under fire in the past. In 2001, another statin drug, Baycol, was removed from the market after it was found to cause a form of severe muscle damage. Baycol was linked to more than 100 deaths.