

# Cholesterol drugs for the healthy still debatable

June 28 2010, By CARLA K. JOHNSON , AP Medical Writer

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(AP) -- Should healthy people with low cholesterol take a pill to lower their cholesterol even more in hopes of preventing heart problems? The question is dividing heart doctors and confusing patients.

An analysis published Monday questions research that led federal regulators to allow the statin drug Crestor wider use for prevention. The [Food and Drug Administration](#) broadened Crestor's market to millions more people in February, partly because of a study reported in 2008 by Crestor's maker.

Consequently, more doctors are putting healthy people on [statin drugs](#), sometimes inappropriately, heart doctors say. And they say too little attention is paid to potential risks, such as developing diabetes.

The earlier Crestor study funded by AstraZeneca PLC was controversial from the start. Its findings: Crestor cut the risk of certain [heart problems](#) in half for the middle-aged and older men and women in the study, who had normal levels of LDL, or "bad" cholesterol (below 130), and high levels of a measure of inflammation called C-reactive protein, CRP. It not only suggested a new use for Crestor, but a new blood test for CRP.

Critics suggested the dramatic results might be exaggerated because the experiment was stopped after two years instead of the planned five. They questioned why the authors didn't report the rates of death from [heart attack](#) and stroke, which when teased out of the data turned out to be unaffected by Crestor.

The new analysis, appearing in Monday's Archives of Internal Medicine, raises those questions again. A second paper in the same journal finds no justification from the earlier results for using a test for CRP to make treatment decisions. And a third paper, an analysis of 11 published studies including the 2008 study, finds no evidence that statins help high-risk people without heart disease live longer.

"Why take a medicine that hasn't been shown to make you feel better or live longer? Yet that's what millions of Americans are doing," said [Archives of Internal Medicine](#) editor Dr. Rita Redberg, a cardiologist at University of California San Francisco.

Cholesterol-lowering drugs, including statins, are among top sellers nationally and globally. More than 238 million prescriptions for cholesterol-lowering drugs were dispensed by retail pharmacies in 2009, with more than \$17 billion in sales, according to the health industry data firm IMS Health.

Statins, which work to clear LDL or "bad" cholesterol from the bloodstream, are widely prescribed for people with existing heart disease. Most experts agree the drugs reduce the risk of death in those patients. What's not clear is how much they help people who may be at risk because they smoke or have high blood pressure, but have no history of [heart disease](#).

If the [AstraZeneca](#) findings were incorporated into treatment guidelines, roughly 6 million more people could be put on statins at a cost of \$9 billion a year.

Dr. Michel de Lorgeril of Grenoble University in France, co-author of the new analysis, said the review showed the earlier results weren't clinically and scientifically consistent and that the study should have continued the full five years.

Dr. Paul Ridker of Harvard-affiliated Brigham and Women's Hospital in Boston, who led the 2008 study, said the study was stopped because the drug was clearly benefiting people in the study. He said the FDA's independent analysis and its approval for Crestor's new use backed up the decision to stop the research early.

Speaking of the critical new analysis, Ridker said: "In the face of overwhelming evidence, the lengths some people will go to avoid dealing with new ideas that unsettle them is quite striking."

An outside expert, Dr. Lisa Schwartz of the Dartmouth Institute for Health Policy and Clinical Practice, said the bottom line for patients is to pay attention to what's still unknown about long-term use of Crestor in healthy people.

"The people in this study only took the drug for under two years. We just don't know what the balance of benefits and harms are for people who are going to take this for a lifetime," Schwartz said.

**More information:** Archives: <http://www.archinternmed.com>

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