

http://www.nytimes.com/2011/05/27/health/policy/27heart.html

patients into tolerating these side effects in hopes that the medicine would save their lives. Now, they will not have to.

Dr. William M. Schreiber, a Louisville, Ky., internist, said he had stopped prescribing niacin because so many patients told him they could not abide its effects. "I'm delighted to hear that statins alone are just as good as statins and niacin," he said.

The study is bad news for the maker of Niaspan, Abbott Laboratories, for the drug industry as a whole and even for the Food and Drug Administration. Abbott last year had \$927 million in Niaspan sales, and the company spent \$32 million on the study (the government spent \$21 million) in the hope that it would increase sales. Instead, the results are bound to lower use of the drug.

<u>In a statement</u>, Dr. Eugene Sun, a vice president at Abbott, said, "Based on its long history of clinical evidence, Niaspan remains an important agent for patients with" blood lipid problems.

The study gives no comfort to other drug makers, many of which have been trying to come up with new drugs to raise levels of good cholesterol or otherwise lower heart attack risks. <u>Statins</u> and other drugs have proven so effective in treating heart disease that improvements are proving very tough to find.

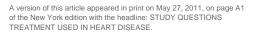
The study is also bad news for the F.D.A., which heavily relies on laboratory results to decide whether to approve drugs.

"This study shows that approving drugs and allowing them to stay on the market on the basis of how they affect <u>lipids</u> and other biomarkers is not good policy," said Dr. Steven Nissen, chairman of cardiovascular medicine at the <u>Cleveland Clinic</u>. "It's time to have a new regulatory approach."

In the trial, 3,414 participants with heart and vascular disease were given either Zocor and a placebo or Zocor and Niaspan and followed for 32 months. The trial ended 18 months early because it was found that there was almost no chance taking Niaspan would prove beneficial. Zocor and other medications did a good job of keeping patients' bad cholesterol levels relatively low.

Researchers said patients should not stop taking Niaspan without talking to their doctors first.

"We have great evidence that lowering L.D.L. is beneficial," said Dr. Bruce Psaty, a professor of medicine and epidemiology at the University of Washington. "We lack good evidence that changing H.D.L. or triglycerides does much."



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