

James Edward Katz, M.D.

Niacin Nonsense

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For ten years, Merck has been pursuing one of the Holy Grails in pharmaceuticals. Aspirin is one of the most recommended drugs in the world. Merck has been developing laropiprant to replace aspirin. But laropiprant was a long shot as it has a paradoxical dose- response relationship; the high dose effects are the reverse of the low dose. Drugs like this do not do well in the real world because the general population does not necessarily follow the curve observed in the lab. Therefore Merck financed a study called THRIVE with 25,000 participants and the results were dreadful. The lead researcher's statement was:

"Results from a landmark study of specially formulated niacin (extended-release niacin plus laropiprant, an anti-flushing agent) in high-risk patients appears to have extinguished any clinical role for niacin to reduce the risk of cardiovascular events in these patients.

Treatment with extended-release niacin plus laropiprant, was associated with an increase in serious adverse events that led to people being hospitalized: a significant increase in hemorrhagic stroke, serious infections, and new onset diabetes."

It is important to understand that niacin-induced flushing can be blocked with aspirin, apple sauce, or quercetin (a protein found in tea, broccoli, blueberries and numerous other foods), along with the avoidance of alcohol and appropriate drug dosing. Why did Merck believe we need a new pharmaceutical?

Should Merck have succeeded, they would have a \$100/month "drug" to replace aspirin, which doesn't even cost \$1/month. Don't laugh, prescription Niaspan costs \$110/month, and it's over-the-counter Slo-Niacin costs about \$14/month. Niaspan sales last year were just under a billion dollars. "FDA Approved" opens insurance reimbursement.

What is a researcher to do when tasked with announcing that a quarter-billion dollar effort on laropiprant has come to naught? Simple, blame it on the niacin! The presentation to the American College of Cardiology was titled "THRIVE May Signal the End for Niacin."

The evidence of the cardiac and vascular benefits of niacin, along with it's safety, have been accumulating for 35 years.

Coronary Drug Project - a study published in 1979 within the New England Journal of Medicine demonstrated a decrease in total cardiac mortality of 11% in the niacin group and a decrease in overall mortality of 14% overall.

The HATS (High density lipoprotein Atherosclerosis Study) published in 2002 within the New England Journal of Medicine demonstrated that the niacin group had one cardiac event for the entire trial and that atherosclerotic lesions in some patients' hearts were reversed, while twenty-five per cent of the control group held cardiac events. The niacin group was followed up five years later and their side effects, such as elevated glucose or uric acid, had all returned to normal. The effects of niacin are amplified if given alongside a statin (Lipitor) type drug.

The ARBITOR-2 Trial showed reduced carotid atherosclerosis with niacin. The Oxford Study showed MRI regression of carotid plaques in the niacin treated patients.

In all of these studies there were no major adverse effects from niacin. At the same time, by itself, or combined with a statin drug, niacin continued to reduce heart attacks, reverse atherosclerosis, and reduce the risk of strokes. And there is standing evidence that niacin may also reduce the risk of Alzheimer's, but I will save that for a future newsletter.

It should be reasonably clear that the problem in the THRIVE trial was Merck's new drug laropiprant, and that niacin's track record over 35 years exonerates it.