

Of Death, Drugs, Recalls, and Arrogance

To pique your interest, first let's start with the arrogance.

“Niacin (nicotinic acid) comes in prescription form and as ‘dietary supplements.’ Dietary supplement niacin is not regulated by the U.S. Food and Drug Administration (FDA) the same way that prescription niacin is. It may contain widely variable amounts of niacin – from none to much more than the label states. The amount of niacin may even vary from lot to lot of the same brand. *Dietary supplement niacin must not be used as a substitute for prescription niacin. It should not be used for lowering cholesterol because of potential very serious side effects.*” (My italics)

Quoted from “Cholesterol-Lowering Drugs” webpage of the American Heart Association (AHA). There is a complete lack of any alternatives to the drugs they recommend, including no mention of inositol hexaniacinate, pantethine, policosanol, or red yeast rice powder.

<http://www.americanheart.org/presenter.jhtml?identifier=163>

Listing all the drug forms for controlling cholesterol levels, this pharmaceutical model promotion by the AHA appears highly suspect in light of product recalls and problems in the pharmaceutical industry. More on AHA arrogance later.

David Graham is the FDA reviewer who warned the arthritis drug Vioxx had been linked to an increased risk of heart attack and stroke. He testified before the U.S. Senate Finance Committee that there were at least five other drugs on the market today that should be seriously scrutinized to determine whether they should remain there. Dr. Graham cited the acne drug Accutane, the weight loss drug Meridia, the anti-cholesterol drug Crestor, the pain reliever Bextra, and the asthma drug Serevent. Accutane and Crestor continue to come under heavy fire from industry watchdogs calling for their recall. Another editorial alone could be written about antidepressants and the court cases involving suicide and murder.

Product recalls over the past few years include the diabetes drug Rezulin and the painkiller Duract – both for causing liver failure – and the cholesterol-lowering statin Baycol, hitting a home run with fatal rhabdomyolysis, 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. At the time of recall, the FDA had received reports of 31 deaths in the United States due to severe rhabdomyolysis associated with the use of Baycol, 12 of which involved concomitant use of gemfibrozil. Gemfibrozil currently remains listed on the AHA webpage quoted above, as one of the AHA's magic bullets.

In a February 2004 love-fest press release, KOS Pharmaceuticals, the manufacturer of Niaspan and Advicor (prescription niacin products), strongly commended the AHA for its stand that dietary supplement niacin should not be used. The press release included KOS product information that includes the following warning – Niaspan preparations should not be substituted for equivalent doses of immediate-release (crystalline) niacin because “Cases of severe toxicity, including fulminant hepatic necrosis, have occurred in patients who have substituted sustained-release (modified release, timed-release) niacin products for immediate-release niacin at equivalent doses.”

So let's get this straight: substituting the AHA-endorsed pharmaceutical, timed-release niacin, for the same dose of the demonic “dietary supplement” niacin, can cause liver toxicity, while the “dietary supplement” niacin does not. Darn those pesky livers; we should cut them all out and make the AHA happy. A review of the literature readily reveals how some sustained-release forms of niacin have caused significant liver toxicity and in some cases liver failure.¹⁻⁵

So let's come back to the AHA arrogance again:

The following quotation is from an FDA warning letter to the aforementioned KOS Pharmaceuticals, the manufacturer of the AHA-endorsed, pharmaceutical timed-release niacin:

“The inspection revealed your firm's Quality and Laboratory systems employed during the manufacture, processing, packing, or holding of Niaspan (niacin extended-release tablets) and Advicor (niacin extended-release tablet cores/lovastatin tablets) do not conform to cGMP.

“For example, your firm’s QCU failed to thoroughly investigate dissolution failures in multiple lots of your Niaspan Extended Release tablets and content uniformity failures found in multiple lots of Advicor tablets.”
<http://www.fda.gov/foi/warningletters/g4502d.htm>

Get out your scissors (watch out for that liver) and cut out the quote from the AHA webpage above. You can then paste the pertinent parts adjacent to the actual facts in the rest of this editorial. You will find nothing left, much like the arrogant argument of the AHA, a vacuous condemnation of everything they have not blessed.

Al Czap
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2. Knopp RH, Ginsberg J, Albers JJ, et al. Contrasting effects of unmodified and time-release forms of niacin on lipoproteins in hyperlipidemic subjects: clues to mechanism of action of niacin. *Metabolism* 1985;34:642-650.
3. Gray DR, Morgan T, Chretien SD, Kashyap ML. Efficacy and safety of controlled-release niacin in dyslipoproteinemic veterans. *Ann Intern Med* 1994;121:252-258.
4. Rader JI, Calvert RJ, Hathcock JN. Hepatic toxicity of unmodified and time-release preparations of niacin. *Am J Med* 1992;92:77-81.
5. Knopp RH. Niacin and hepatic failure. *Ann Intern Med* 1989;111:769.