Prescription fish-oil remains approved for triglycerides, but not for cholesterol

By ACSH Staff — October 18, 2013

[1] Given the long-held belief in the anti-inflammatory and heart healthy effects [2] of long-chain omega-3 fatty acids, especially as found in fish oil, the findings of a 2011 study [3] showing that Amarin's prescription eicosapantaenoic acid (EPA) fish oil, icosapent ethyl (Vascepa), reduced markedly elevated triglyceride levels over 500, with normal levels in the 75-200 range came as no surprise. In fact, the FDA approved the preparation in 2012. Subsequently, another trial [4] showed substantial efficacy among patients with triglyceride levels in the 200-500 range.

Thus, the company, after performing yet another study [5] to determine if the omega-3 preparation also helped lower LDL-cholesterol levels, applied to the FDA for approval to market the drug as a cholesterol agent as well. That trial, which is still underway, includes high-risk patients with mixed lipid abnormalities who are taking statins, and compares the effects of Vascepa versus placebo on a composite of cardiovascular death, heart attack, stroke, coronary revascularization, and hospitalization for unstable angina. Final results aren't expected until November 2016.

The FDA's panel report [6] did not find sufficient evidence to approve Vascepa for the requested labeling indication. They expressed concern over the lack of evidence that cardiovascular outcomes [7] are improved with fish oil -- or any other non-statin lipid-modulating agents for that matter.

So it appears that the results of the latter trial known as the REDUCE IT trial although still years away, will be needed before the FDA grants an expanded indication to Vascepa.

ACSH's Dr. Gilbert Ross added, When I practiced rheumatology, fish oil was all the rage among many arthritis patients as a pain reliever and anti-inflammatory agent with few side effects. Unfortunately, the solid evidence of its benefit remains flimsy. The analogous role long-chain fatty acids are hoped to play as heart healthy dietary supplements is similarly soft, although the data on its ability to lower triglycerides one of the fatty components in the blood with some adverse heart effects if high enough seems well-established. I doubt it will prove highly efficacious for reducing bad LDL cholesterol, but we shall be finding out within the next few years. I think the FDA's panel
decision is sound at this time.

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