Is the FDA ignoring heart risks from high triglycerides in the face of mounting evidence to the contrary?

The lives of millions of Americans are potentially at risk.

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The EPA Drug Initiative (EPADI) urges the FDA to thoughtfully consider new and almost irrefutable proof that high triglycerides are a significant risk factor contributing to cardiovascular disease-related death and morbidity.

This past week, two independent studies were published in the prestigious New England Journal of Medicine (NEJM), both drawing the same conclusion: that reducing serum triglycerides to accepted, safe levels resulted in a 40% decrease in cardiovascular risk. These trial results are being universally hailed as groundbreaking, as they focus on people having a certain gene mutation, which elegantly eliminates all cardiovascular disease risk factors other than serum triglyceride levels. Both studies—from well-respected researchers—have caught the attention of the world, with the results being published by prominent news media including the New York Times and Forbes.

Current guidelines from The American Association of Clinical Endocrinologists, The American Diabetes Association, and the National Institutes of Health all recognize that high triglycerides are a risk factor for cardiovascular disease, as well as diabetes and stroke.

The NEJM-published studies add to the growing consensus within the medical community of the risks associated with high triglycerides. Despite this, the FDA does not concur, needlessly placing millions of Americans at unnecessary risk. In a surprising and controversial move in October 2013, the FDA changed its mind on triglyceride risk stating it “no longer considers a change in serum triglyceride levels as sufficient to establish the effectiveness of a drug intended to reduce cardiovascular risk in subjects with serum triglyceride levels below 500 mg/dL.” As such, the FDA's current policy on this issue is wholly inconsistent with the guidelines established by the aforementioned medical associations, and is directly contradicted by the new data published last week in the NEJM.

The two landmark studies revealed that people whose triglycerides average 350 mg/dL have a very significant, increased risk of heart attack, which is considerably lower than what the FDA deems safe. The US Congress is now investigating the circumstances pertaining to why the FDA made this statement, as well as the abrupt manner in which the FDA changed its view on the risks of triglycerides.

The FDA's current position denies Americans full access to what could be the most effective and safe triglyceride-lowering drug ever produced. The drug, Vascepa, is an Omega-3 derivative, which is significantly differentiated from other Omega-3 drugs in that it lowers triglycerides without raising bad LDL cholesterol. Furthermore, Vascepa significantly lowers APOC III, a risk factor in the blood on which the NEJM studies primarily focused. Currently, Vascepa is only approved by the FDA for use in people whose triglyceride levels are at the extremely high-risk threshold of 500 mg/dL or above. This group represents only a small percentage of Americans whose triglyceride levels put them at risk of a heart attack, as noted in the NEJM studies.

EPADI applauds Congressional concern with respect to the FDA's continued reliance on flawed science in denying Vascepa's full approval for Americans at risk due to high triglycerides in the 200 to 499 mg/dL range. EPADI calls on newly appointed HHS Secretary, Sylvia Burwell and Agency Commissioner, Margaret Hamburg, MD to publicly respond to and incorporate this new and compelling study data, in correcting the FDA's conclusion related to the risk of triglycerides on cardiovascular disease.

EPADI is convinced wider approval of Vascepa could help save the lives of millions who are currently being denied by the FDA full access—including insurance coverage—to this very safe, very effective triglyceride-lowering therapy.

All of this is perhaps best summed up by the statement of Cardiologist Ethan J. Weiss, MD, associate professor at the University of California, San Francisco, in the Forbes article in which he stated: "In medical school we were told to ignore triglycerides and focus on HDL,' he said, 'It turns out that we probably had it backwards, and that we should be paying attention to triglycerides and ignoring HDL.'"

Please visit www.epadruginitiative.com for more information and learn how you can help by adding your voice to the call for the FDA to correct their position, and instead embrace the treatment of high triglycerides for those patients at risk from heart disease.

The EPA Drug Initiative
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