What is Amarin doing to protect the Vascepa® franchise against dietary supplement manufacturers that mislead the public by referencing REDUCE-IT™ or Vascepa®?

Amarin is fully committed to defending the Vascepa® franchise against any company that seeks to mislead the public and cardiovascular patients in need by fraudulently leveraging the landmark REDUCE-IT™ study results or the REDUCE-IT™ or Vascepa® names for profit. Amarin is prepared to file multiple lawsuits should it become aware of any such claims.

For example, on October 29, 2018, Amarin filed two lawsuits in U.S. federal court, each against a different dietary supplement company for unlawfully using the results from Amarin's landmark REDUCE-IT™ cardiovascular outcomes study of Vascepa® to falsely and deceptively claim that their omega-3 dietary supplement products are effective in reducing cardiovascular risk. The defendants in the cases were Omax Health, Inc. and The Coromega Company, Inc.

In April 2019, Omax and Coromega settled these litigations under terms by which Omax and Coromega agreed to substantially all the demands in Amarin's complaints. Under the settlements, Coromega and Omax agreed to publicly correct their prior statements that wrongly suggested Amarin's REDUCE-IT™ cardiovascular outcomes trial supports the safety and efficacy of omega-3 dietary supplements. Each dietary supplement company also acknowledged that as a general matter under federal law dietary supplements may be lawfully marketed to supplement the diet, but they cannot be lawfully marketed to treat, mitigate, or prevent disease, such as cardiovascular disease.

As the Coromega and Omax corrective statements make clear, the REDUCE-IT™ study is applicable only to Vascepa®, an FDA-approved drug comprised of icosapent ethyl, a single omega-3 acid, and was not designed to test the efficacy of any dietary supplement. The corrective statements also make clear that federal law prohibits dietary supplement companies, like Omax and Coromega, from claiming their dietary supplements treat, mitigate or prevent disease, such as cardiovascular disease, and from suggesting dietary supplements are substitutes for disease therapies, like Vascepa®. Additionally, and consistent with the corrective statements, the settlements bar Coromega and Omax from:

- suggesting that the REDUCE-IT™ study (or any other Amarin study of Vascepa®) implies use of their omega-3 dietary supplement products would have similar results;
- making any statements regarding the comparability, substitutability, or superiority of each company's omega-3 products to Vascepa®; and
- claiming that their omega-3 dietary supplements lower or reduce high triglycerides.

Vascepa® is materially different from these products:

1. Vascepa® is proven to lower cardiovascular risk based on the REDUCE-IT™ cardiovascular outcomes study whereas three recent meta-analyses published in highly respected medical journals show that there is no scientific consensus that omega-3 dietary supplements have any beneficial effect on cardiovascular disease risks, or even cardiovascular health more generally[1];

[1] *See*

2. Vascepa® is an FDA-approved drug designated by FDA as a new chemical entity based on its unique molecular structure;
3. The active ingredient in Vascepa® is icosapent ethyl and not a mixture of omega-3 acids;
4. Because omega-3 fatty acids are highly prone to oxidation (i.e., spoilage), Vascepa® is manufactured, encapsulated and packaged through a stringent and complex FDA-regulated process designed to effectively eliminate impurities and isolate and protect the fragile single molecule active ingredient from degradation;
5. Vascepa® was developed as a prescription-only drug to be administered in high dosages and has a demonstrated safety profile; and
6. Vascepa® is promoted for use in populations for which it has been proven to be safe and effective (for example, adult patients with severe hypertriglyceridemia).

The foregoing information is qualified in its entirety by Amarin's complaints and related documents, copies of the complaints are available **here** (Coromega) and **here** (Omax).

Settlement documents for Coromega are available: **here**, **here** and **here** .

Settlement documents for Omax are available: **here**, **here**, and **here**.

Updated May 7, 2019

- David S. Siscovick et. al, *Omega-3 Polyunsaturated Fatty Acid (Fish Oil) Supplementation and the Prevention of Clinical Cardiovascular Disease: A Science Advisory From the American Heart Association*, 135 Circulation e867–e884, Table 8 (2017), http://circ.ahajournals.org/content/early/2017/03/13/CIR.0000000000000482 ("available evidence does not support the use of [omega-3] supplements in the general population who are not at high risk for [cardiovascular disease]"); *see also* Ethan M. Balk et. al, Omega-3 Fatty Acids and Cardiovascular Disease: An Updated Systematic Review vi, (Evidence Report/Technology Assessment, Number 223), (Aug. 2016), https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/fatty-acids-cardiovascular-disease_research.pdf (last accessed Oct. 26, 2018) (concluding that omega-3 supplements do not affect "major adverse [cardiovascular] events, all-cause death, sudden cardiac death, coronary revascularization, atrial fibrillation, or [blood pressure]" *in populations at risk for, or with cardiovascular disease*, or in "general healthy populations")
- Asmaa S. Abdelhamid, et al., Omega-3 Fatty Acids for the Primary and Secondary Prevention of Cardiovascular Disease, COCHRANE DATABASE OF SYSTEMATIC REVIEWS (July 2018), https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003177.pub3/full ("There is evidence that taking omega-3 capsules does not reduce heart disease, stroke or death.")
- Theingi Aung, et al., *Associations of Omega-3 Fatty Acid Supplement Use with Cardiovascular Disease Risks: Meta-analysis of 10 Trials Involving 77,917 Individuals*, 3 JAMA Cardiology (Jan. 31, 2018), https://jamanetwork.com/journals/jamacardiology/fullarticle/2670752. After reviewing 10 studies involving 77,917 patients, the authors stated that "[t]his meta-analysis demonstrated that omega-3 fatty acids had no significant association with fatal or nonfatal coronary heart disease or any major vascular events. It provides no support for current recommendations for the use of such supplements in people with a history of [CHD]." *Id.*