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

On October 29, 2018, Amarin filed lawsuits against dietary supplement companies seeking to unlawfully leverage REDUCE-IT™ results.

On October 29, 2018, Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd., each wholly-owned subsidiaries of Amarin Corporation plc (Nasdaq: AMRN), 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® (icosapent ethyl) capsules, among other marketing messages, to falsely and deceptively claim that their omega-3 dietary supplement products are effective for reducing cardiovascular risk. Amarin brought the lawsuits under the federal Lanham Act, which protects commercial interests against unfair trade practices in the United States, and the California Unfair Competition Law ("UCL"), another unfair trade practice statute. The defendants in the cases are Omax Health, Inc. and The Coromega Company Inc.

"With REDUCE-IT™ results in hand, Amarin is fully committed to defending the Vascepa® franchise against outlier dietary supplement and any drug companies that seek 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," commented Joseph Kennedy, Amarin executive vice president, general counsel. "Amarin is prepared to file multiple new lawsuits should it become aware of any similar claims."

Vascepa is materially different from dietary supplements such as the defendants' products because:

1. Vascepa® is proven to lower cardiovascular risk based on the $360 million REDUCE-IT cardiovascular outcomes study;
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).

In fact, three recent meta-analyses published in highly respected medical journals show that there is no scientific consensus that omega-3 dietary supplements like those sold by the defendants have any beneficial effect on cardiovascular disease risks, or even cardiovascular health more generally.[1]

In the lawsuits, Amarin seeks the following remedies:

1. A permanent injunction prohibiting the unlawful and unfair practices.
2. A judgment finding violation of the Lanham Act, 15 U.S.C. § 1051, et seq.;
3. A judgment finding violation of California Business and Professions Code section 17200, et seq.;
4. Damages, corrective advertising costs, profits and other monetary relief according to proof;
5. Declaratory relief;
6. Attorneys' fees and costs incurred;
7. Prejudgment interest; and
8. Any further relief the Court may deem just and proper.

Vascepa® is a low-cost drug. The majority of patients covered by insurance who obtain prescriptions for Vascepa® pay a monthly co-pay charge of $9.99 or less. A patient with commercial insurance can pay as little as $9.00 for a 90-day supply prescription of Vascepa®.

The foregoing information is qualified in its entirety by Amarin's complaints and related documents, copies of the complaints are available **here** and **here**. Amarin's complaint and other litigation documents

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[1] *See*

- 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.*

are also expected to be available to the public throughout the litigation through Public Access to Court Electronic Records (PACER), the federal court online docketing system.