UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ANDREA TRUJILLO,
Plaintiff,

v.

WALGREEN CO.,
Defendant.

No. 13 CV 1852
Judge James B. Zagel

MEMORANDUM OPINION AND ORDER

Plaintiff filed a two-count Second Amended Complaint under the California Business and Professions Code and the California Consumer Legal Remedies Act based on alleged false and misleading statements that appear on the bottle of a Vitamin E supplement produced and sold by Defendant. Before the Court is Defendant's motion to dismiss. For the following reasons Defendant's motion is GRANTED.

1. Background

Defendant manufactures, sells, and distributes Walgreens Vitamin E 400 IU Dietary Supplement (the "Product"). The Product is sold in a bottle on which the following statement appears: "Vitamin E naturally contributes to cardiovascular health by helping to protect LDL cholesterol from oxidation which may cause cellular damage" (the "Statement"). Below the Statement appears the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure, or prevent any disease" (the "Disclaimer").

Plaintiff alleges that the Statement is false and that numerous scientific studies have proven that Vitamin E supplements do not contribute to cardiovascular health. She further

alleges that she relied on the Statement in purchasing numerous bottles of the Product, which she would not have done had she known that the Statement was false. Plaintiff purports to represent herself and all other customers across the United States who have purchased the Product due to reliance upon the Statement.

2. Analysis

There are several problems with the Second Amended Complaint. I am going to focus on one: it is preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). Since 1990, the FDCA, 21 U.S.C. § 301 *et seq*., through the Nutrition Labeling and Education Act of 1990 (NLEA"), 21 U.S.C. § 343, 343-1(a)(5), has contained an express preemption provision which prohibits states from imposing, directly or indirectly, requirements as to labels like the Statement that is not identical to the federal requirements. 21 U.S.C. § 343-1(a)(5).

The federal requirement for dietary supplements, such as the Product, provides, in pertinent part:

> [A] statement for a dietary supplement may be made if—(A) the statement . . . describes the role of a nutrient or dietary ingredient intended to affect the structure or functions in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient, (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and (C) the statement contains, prominently displayed in boldface type, the following: 'This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

21 U.S.C. § 343(r)(6). If a statement for a food product satisfies federal labeling requirements, the NLEA's express preemption clause precludes state law consumer fraud claims. *See, e.g.*, *Turek v. General Mills, Inc.*, 754 F.Supp.2d 956, 961-62 (N.D. Ill. 2010).

It is facially apparent that the Product satisfies § 343(r)(6)'s criteria. First, the Statement describes the role of Vitamin E (a nutrient)—not the supplement itself—intended to affect the

structure or functions in humans. Vitamin E is an antioxidant, and antioxidants are believed to inhibit cell-damaging oxidation, as well as atherosclerosis, or accumulation of fatty materials in the blood vessels, which obviously contributes to cardiovascular health. Second, the Statement is substantiated by the very studies that Plaintiff relies on in the Second Amended Complaint. *See* Lee, I-Min, et al., *Vitamin E in the Primary Prevention of Cardiovascular Disease and Cancer. The Women's Health Study: A Randomized Controlled Trial*, 294(1) JAMA 56 (July 6, 2005) ("In some, but not all, basic research reports, vitamin E supplementation retarded atherogenesis"); Sesso, H.D., et al. *Vitamins E and C in the Prevention of Cardiovascular Disease in Men. The Physicians' Health Study II Randomized Controlled Trial*, 300(18) JAMA 2123 (November 12, 2008) ("Basic research studies suggest that vitamin E, vitamin C, and other antioxidants reduce cardiovascular disease by trapping organic free radicals, by deactivating excited oxygen molecules, or both, to prevent tissue damage"); Lonn, E., et al., *Effect of Long-Term Vitamin E Supplementation On Cardiovascular Events And Cancer: A randomized Controlled Trial*, 293(11) JAMA 1338 (Nov. 12, 2008) ("In humans, [Vitamin E] can improve endothelial [the inner lining of blood vessels] function. Epidemiological data indicate an inverse association between cardiovascular risk and vitamin E intake from dietary sources and/or supplements"). Third, there is no dispute that the Disclaimer perfectly tracks the language required under § 343(r)(6)(C). The upshot is that even if Plaintiff could adequately plead fraud under Rule 9(b)—which she cannot—her claims would be preempted.

Plaintiff appears to believe that the Statement's assertion that Vitamin E "naturally contributes to cardiovascular health" is necessarily rendered false by certain studies that suggest Vitamin E may have little to no impact in preventing major cardiovascular events. Assuming these studies are correct, it is not inconsistent to say that a nutrient "contributes" to good

cardiovascular health but cannot prevent major cardiovascular diseases—which is precisely why Congress deliberately included *both* subcomponents (A) and (C) under § 343(r)(6).

Plaintiff attempts to analogize this case to my ruling in *Pearson v. Target Corp.*, No. 11 CV 7972, 2012 WL 7761986 (N.D. Ill. Nov. 9, 2012). In *Pearson*, I refused to dismiss certain claims brought under the Illinois Consumer Fraud and Deceptive Practices Act based on alleged false representations that appeared on bottles of a dietary supplement containing Glucosamine and Chondroitin. *Pearson* is materially distinguishable from this case. The Plaintiff in *Pearson* argued that there was no substantiation for the claim that Glucosamine and Chondroitin affected the structure or function of the human body in the way that the products' labeling claimed ("maintain the structural integrity of joints," "help rebuild cartilage," and "lubricate joints.") In other words, the statement of the nutrients' intended effect was alleged to be misleading because there was no scientific evidence to confirm that the nutrient could have the claimed effect on the human body. Taking that allegation as true, I found that the defendant could not shield itself from liability for a misleading and unsubstantiated statement by slapping on the FDA disclaimer.

Here, by contrast, Plaintiff does not dispute that Vitamin E is an antioxidant, nor does she dispute that antioxidants have been shown to contribute to cardiovascular health (again, the Second Amended Complaint cites several studies that confirm this). Instead, Plaintiff claims that the Statement is misleading because some studies suggest that Vitamin E supplements are ineffective in preventing major cardiovascular diseases. Again, stating that a nutrient "contributes to health" is not equivalent to stating that it "cures disease"—and just in case that is not apparent to the consumer, the FDA disclaimer purposefully targets this conceptual conflation. This case would be on all fours with *Pearson* if there was no scientific substantiation for the claim that antioxidants contribute to cardiovascular health, but Plaintiff has effectively

pled herself out of Court on that claim.

The case is dismissed with prejudice.

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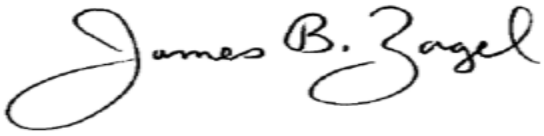

James B. Zagel
United States District Judge

DATE: August 9, 2013