# United States Court of Appeals
## For the First Circuit

No. 16-1199

RONDA KAUFMAN,
on behalf of herself and all others similarly situated,

Plaintiff, Appellant,

v.

CVS CAREMARK CORPORATION; CVS PHARMACY, INC.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

[Hon. Mary M. Lisi, U.S. District Judge]

Before

Torruella, Kayatta, and Barron,
Circuit Judges.

Brian D. Penny, with whom Goldman Scarlato & Penny, P.C., was on brief, for appellant.

Robert M. Andalman, with whom A&G Law LLC was on brief, for appellees.

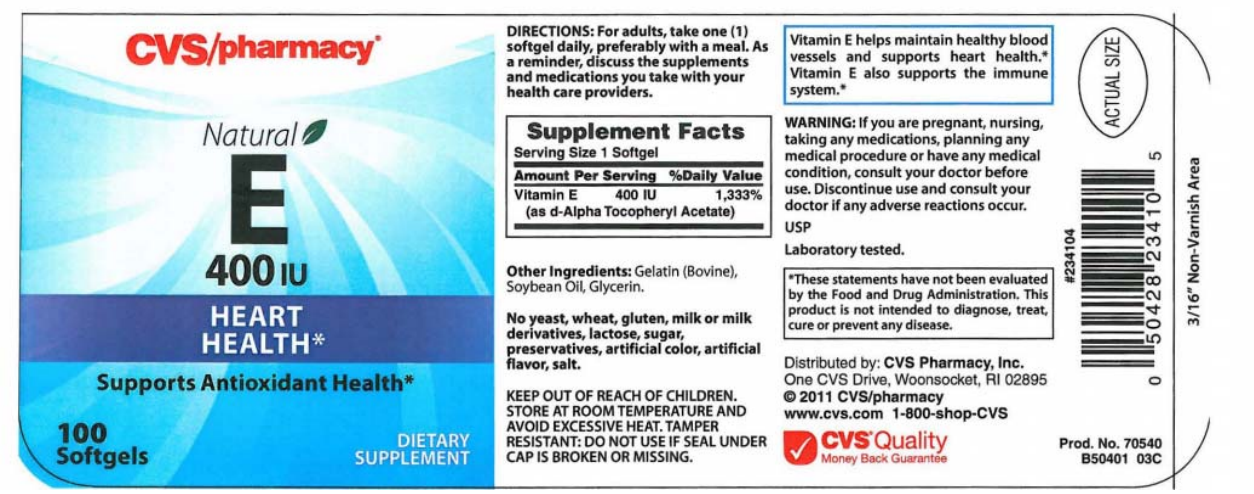
September 6, 2016

**KAYATTA**, **Circuit Judge**. CVS Pharmacy, Inc. ("CVS") sells a Vitamin E dietary supplement with a label that touts the product as supporting "heart health." Having purchased CVS's Vitamin E product, Ronda Kaufman alleges that CVS's label deceives consumers because no scientifically valid studies show that the label's "heart health" statements are both truthful and not misleading. Finding that federal law does not preempt Kaufman's effort to maintain this action under New York's consumer protection law, we reverse the district court's order dismissing Kaufman's complaint.

## I. Background

Because the district court dismissed this lawsuit on a motion to dismiss for failure to state a claim, Fed. R. Civ. P. 12(b)(6), our review is de novo and we assume that the facts alleged in the complaint, plus reasonable inferences drawn from those facts, are true. In re Celexa & Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 39 (1st Cir. 2015).

Ronda Kaufman purchased CVS-brand Vitamin E 400 International Units ("IU") Softgels (100 count) at a CVS located in Plainview, New York. The bottle containing the Vitamin E product bore the following label:




Kaufman alleges that in deciding to purchase the product, she relied on the label.

Kaufman now claims that there are no scientifically valid studies supporting CVS's "heart health" statements. Rather, she alleges that various studies[1] evaluating Vitamin E "demonstrate that vitamin E and vitamin E supplementation offer no

[1] Stephen P. Fortmann et al., Vitamin and Mineral Supplements in the Primary Prevention of Cardiovascular Disease and Cancer: An Updated Systematic Evidence Review for the U.S. Preventive Services Task Force, 159 Annals of Internal Med. 824 (2013); I-Min Lee et al., Vitamin E in the Primary Prevention of Cardiovascular Disease and Cancer--The Women's Health Study: A Randomized Controlled Trial, 294 J. Am. Med. Ass'n 56 (2005); Eva Lonn et al., Effects of Long-Term Vitamin E Supplementation on Cardiovascular Events and Cancer: A Randomized Controlled Trial, 293 J. Am. Med. Ass'n 1338 (2005); Edgar R. Miller III et al., Meta-Analysis: High-Dosage Vitamin E Supplementation May Increase All-Cause Mortality, 142 Annals of Internal Med. 37 (2005); Howard D. Sesso et al., Vitamins E and C in the Prevention of Cardiovascular Disease in Men--The Physicians' Health Study II Randomized Controlled Trial, 300 J. Am. Med. Ass'n 2123 (2008); Paul G. Shekelle et al., Effect of Supplemental Vitamin E for the Prevention and Treatment of Cardiovascular Disease, 19 J. Gen. Internal Med. 380 (2004); Salim Yusuf et al., Vitamin E Supplementation and Cardiovascular Events in High-Risk Patients, 342 New Eng. J. Med. 154 (2000).

cardiovascular benefit" and "do[] not reduce the risk of suffering a cardiovascular event, such as a heart attack, nor [do they] reduce the risk of dying from cardiovascular disease." She adds that one study reflects "that those taking vitamin E had higher rates of heart failure and were more likely to be hospitalized for heart failure," while another study found "an increase in mortality that progressively increased as daily dosage exceeds 150 iu." The complaint further states that "[a]ll variations of [CVS's] pill-type vitamin E products exceed the 150 iu level shown to increase mortality in this study." As a result, she alleges, CVS's representation that its product supports heart health is misleading.

Kaufman marshalled these allegations in service of a putative class action complaint that advances two counts at issue on appeal: violation of the New York Consumer Protection Act, N.Y. Gen. Bus. Law § 349 ("NYCPA section 349"), which makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service" in New York, id. § 349(a), and a piggy-back common law claim of unjust enrichment. The district court found that federal law preempts both of these statements because CVS's label on its Vitamin E product complied with labeling requirements for dietary supplements under the Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq.; see also id. § 343-1(a)(5). Kaufman v.

CVS Caremark Corp., No. 14-216-ML, 2016 WL 347324, at *8 (D.R.I. Jan. 28, 2016).

## II. Discussion

The parties initially debate whether the district court erred in requiring Kaufman to state with particularity the circumstances constituting the alleged deception at issue in this case under Federal Rule of Civil Procedure 9(b). We agree with CVS that Kaufman waived any objection to that requirement, having failed twice to argue in the district court that Rule 9(b) did not apply. See United States v. Argentine, 814 F.2d 783, 791 (1st Cir. 1987). At the same time, we also find that the applicability of Rule 9(b) has no bearing on any possible disposition of this appeal. The circumstances to be stated with particularity under Rule 9(b) generally consist of "the who, what, where, and when of the allegedly [misleading] representation." Alt. Sys. Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 29 (1st Cir. 2004) (quoting Powers v. Bos. Cooper Corp., 926 F.2d 109, 111 (1st Cir. 1991)). CVS makes no argument that the complaint fails to provide this particularity. And, indeed, it does contain sufficient particularity: CVS is the "who"; the heart health statements are the "what"; the label is the "where"; and the occasion on which Kaufman purchased the product is the "when." Therefore, as CVS acknowledges, "[t]he District Court's decision did not turn on

whether the applicable pleading standard was pursuant to Fed. R. Civ. P. 8(a) or 9(b)." Neither does our decision.

Rather, the pivotal question on this appeal is whether Kaufman's complaint plausibly describes conduct by CVS that fell outside the preemptive safe harbor provided by federal law.

**A. FDCA Preemption**

The FDCA circumscribes Kaufman's ability to bring this claim against CVS. Section 343-1(a)(5) of the FDCA provides that no state may "establish . . . any requirement respecting any claim of the type described in section 343(r)(1) of [the FDCA], made in the label or labeling of food that is not identical to the requirement of section 343(r)." 21 U.S.C. § 343-1(a)(5). Section 343(r)(1), in turn, governs statements, among others, that concern a nutrient's relationship "to a disease or a health-related condition."[2] Id. § 343(r)(1)(B). The parties agree (and we therefore assume) that section 343(r)(6), which provides the requirements for statements made on labels of dietary supplements, relates back to section 343(r)(1)(B), and section 343(r)(6)

[2] The regulations promulgated by the FDA define a "[d]isease or health-related condition" as "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension)." 21 C.F.R. § 101.14(a)(5). A health claim, in turn, is defined as "any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." Id. § 101.14(a)(1).

statements are therefore governed by section 343-1(a)(5) preemption. Effectively adding belt to suspenders, the New York law under which Kaufman seeks to proceed independently welcomes the preemptive force of the federal statute, providing that compliance with applicable federal rules and regulations provides a "complete defense" to a claim under NYCPA section 349(a). N.Y. Gen. Bus. Law § 349(d). On all of this, the parties agree.

The net effect of the foregoing is that CVS must prevail if its label satisfies the requirements of FDCA section 343(r), but neither federal nor state law poses any bar to recovery under NYCPA section 349 to the extent that recovery is predicated on a failure by CVS to comply with the requirements of FDCA section 343(r). Accordingly, we turn our attention to determining whether the complaint plausibly alleges conduct by CVS that violates the requirements of FDCA section 343(r).

**B. Compliance with FDCA Labeling Requirements**

> Section 343(r)(6) of the FDCA provides that
>
> 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 function in humans . . . ,
>
> (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

> (C) the statement contains, prominently displayed and 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.".
>
> A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

21 U.S.C. § 343(r)(6).

CVS's label for its 400 IU Vitamin E supplement makes four statements that are subject to the requirements of section 343(r)(6): that Vitamin E "supports antioxidant health"; that Vitamin E helps "maintain healthy blood vessels"; that Vitamin E "supports heart health"; and that Vitamin E "supports the immune system." The parties agree--and we therefore presume without deciding--that these statements are all what the Food and Drug Administration ("FDA") calls "structure/function claims" under FDCA section 343(r)(6)(A). See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000, 1002 (Jan. 6, 2000) (codified at 21 C.F.R. pt. 101). So-called structure/function claims are statements that "describe[] the role

of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 U.S.C. § 343(r)(6)(A). The manufacturer of a dietary supplement may make such statements if the manufacturer both "has substantiation that such statement is truthful and not misleading," id. § 343(r)(6)(B), and includes on the label a prominent disclaimer stating that the FDA has not evaluated the label's statement and that the "product is not intended to diagnose, treat, cure, or prevent any disease," id. § 343(r)(6)(C). The parties agree, and we therefore again assume without deciding, that the label in this case contains just such a disclaimer. We therefore limit our inquiry to determining whether the complaint plausibly alleges that CVS lacks "substantiation" that the "support" and/or "maintain" structure/function statements are "truthful and not misleading."

In urging an affirmative answer to this question, Kaufman offers no developed argument that CVS lacks substantiation that Vitamin E functions as an antioxidant. Kaufman also does not develop any argument that challenges the sufficiency of CVS's substantiation of the statements that Vitamin E supports the immune system or that it helps maintain healthy blood vessels. Instead, training her critique on the label's several statements that Vitamin E "supports heart health," Kaufman asserts that there exists no substantiation that such a description of the nutrient's function is truthful and not misleading.

The FDCA does not define the term "substantiation." FDA guidance, however, advances a common sense interpretation of "substantiation," also adopted by the Federal Trade Commission, as meaning "competent and reliable scientific evidence." Food & Drug Admin., Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act Part I.B. (Dec. 2008), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm (last accessed Aug. 22, 2016) (hereinafter "Guidance for Industry"). Kaufman's express allegation that there are no "scientifically valid studies" substantiating CVS's heart health statements fairly implies that CVS has no competent and reliable evidence to support its heart health statements.[3] This allegation would normally

[3] Paragraph 1 of the complaint reads:

> CVS markets, sells, and distributes six versions of vitamin E supplements. On all vitamin E packages, Defendants represent the product is intended for "heart health." However, numerous double-blind, placebo-controlled studies demonstrate that vitamin E and vitamin E supplementation offer no cardiovascular benefit. Vitamin E does not reduce the risk of suffering a cardiovascular event, such as a heart attack, nor does it reduce the risk of dying from cardiovascular disease. There are no comparable, scientifically valid studies supporting Defendants' representation.

We read "representation" in the last sentence as referring to what

suffice to save from preemption Kaufman's attempt to impose liability on CVS for misleading customers because the imposition of such a liability would not establish any requirement that differs from the requirement of section 343(r)(6)(B)--that CVS must have substantiation for its heart health statements. See 21 U.S.C. § 343-1(a)(5); Dachauer v. NBTY, Inc., No. 16-cv-00216-VC, 2016 WL 3176612, at *1 (N.D. Cal. June 3, 2016).[4]

CVS, however, contends that Kaufman effectively shot herself in the foot by describing in the complaint seven studies of Vitamin E that, CVS argues, provide the required substantiation. See Trujillo v. Walgreen Co., No. 13 CV 1852, 2013 WL 4047717, at *3 (N.D. Ill. Aug. 9, 2013) (plaintiff "effectively pled herself out of Court" by not disputing that Vitamin E is an antioxidant and that antioxidants have been shown to contribute to cardiovascular health). In CVS's words, the studies show Vitamin E's "salutary functions in the body" are "scientific fact."

We agree with CVS that the district court's, and now our, consideration of the studies cited in the complaint is

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CVS is said to "represent" in the first sentence (the heart health statement that the parties agree is a function/structure claim).

[4] A 2012 report by the Inspector General revealed that many dietary supplements failed to meet federal requirements for making structure/function claims. Daniel R. Levinson, Inspector General, Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements (Oct. 2012), https://oig.hhs.gov/oei/reports/oei-01-11-00210.pdf.

appropriate even under Rule 12(b)(6) where the complaint itself directly references and purports to summarize the studies. See Giragosian v. Bettencourt, 614 F.3d 25, 27–28 (1st Cir. 2010). That consideration though, provides no license to engage at this stage of litigation in rejecting plausible readings of those studies. See Abdallah v. Bain Capital LLC, 752 F.3d 114, 119 (1st Cir. 2014) ("no fact finding" in assessing complaint under Rule 12(b)(6)). Rather, we look at the studies for a limited purpose: do the studies on their face render implausible Kaufman's claim that there exist no scientifically valid studies establishing that CVS's heart health statements are truthful and not misleading? For at least two independent reasons, they do not.

First, read in chronological order and with attention to what they presume and what they find, the studies do not support a judicial declaration under Rule 12(b)(6), unaided by expert testimony, that they substantiate the heart health statements. As CVS itself concedes, none of the studies were designed to test the statement that Vitamin E functions to support heart health. Rather, most of the studies presumed that to be so, and instead tested the hypothesis that Vitamin E prevents certain diseases. See, e.g., I-Min Lee et al., Vitamin E in the Primary Prevention of Cardiovascular Disease and Cancer--The Women's Health Study: A Randomized Controlled Trial, 294 J. Am. Med. Ass'n 56, 56 (2005)

("Vitamin E has antioxidant properties . . . leading to the hypothesis that it can prevent [cardiovascular disease]." (emphasis supplied)); Eva Lonn et al., Effects of Long-Term Vitamin E Supplementation on Cardiovascular Events and Cancer: A Randomized Controlled Trial, 293 J. Am. Med. Ass'n 1338, 1338 (2005) ("Epidemiological data indicate an inverse association between cardiovascular risk and vitamin E intake from dietary sources and/or supplements." (emphasis supplied)); Edgar R. Miller III et al., Meta-Analysis: High-Dosage Vitamin E Supplementation May Increase All-Cause Mortality, 142 Annals of Internal Med. 37, 37 (2005) ("On the basis of the premise that vitamin E reduces oxidative stress, many clinical trials have tested vitamin E supplementation as a therapy to prevent various chronic diseases." (emphasis supplied)); Howard D. Sesso et al., Vitamins E and C in the Prevention of Cardiovascular Disease in Men--The Physicians' Health Study II Randomized Controlled Trial, 300 J. Am. Med. Ass'n 2123, 2123 (2008) ("Basic research studies suggest that vitamin E . . . and other antioxidants reduce cardiovascular disease by trapping organic free radicals, by deactivating excited oxygen molecules, or both, to prevent tissue damage." (emphasis supplied)); Paul G. Shekelle et al., Effect of Supplemental Vitamin E for the Prevention and Treatment of Cardiovascular Disease, 19 J. Gen. Internal Med. 380, 380 (2004) (referencing literature "suggest[ing] a beneficial effect of antioxidant-rich foods, as

well as specific antioxidants," such as Vitamin E (emphasis supplied)); Salim Yusuf et al., Vitamin E Supplementation and Cardiovascular Events in High-Risk Patients, 342 New Eng. J. Med. 154, 154 (2000) ("Observational and experimental studies suggest that the amount of vitamin E ingested in food and in supplements is associated with a lower risk of coronary heart disease and atherosclerosis" (emphasis supplied)).

Second, the studies Kaufman cites, including the results of a randomized controlled trial,[5] are also plausibly construed, in the aggregate, as indicating that Vitamin E, in dosages such as that packaged by CVS, can even damage the heart. One study, for example, found that in some populations, increasing Vitamin E intake by supplementation may increase the risk for heart failure. See Lonn et al., supra page 12, at 1346. And another found that "high-dosage" Vitamin E supplements of 400 IU or more--the very dosage that Kaufman purchased--may increase all-cause mortality. Miller III et al., supra page 13, at 37, 40. This indication, which the studies at least render plausible, would seem to mean that Vitamin E can play a role in harming heart health.

[5] See Lonn et al., supra note 1. The FDA has indicated that such trials are the "gold standard," whereas animal studies and in vitro studies such as those relied on by CVS and the district court cannot, by themselves, provide adequate substantiation. See Guidance for Industry, supra page 10.

The statute grants CVS a preemptive license to describe in its label "the role of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A) (emphasis supplied). In so doing, Congress did not similarly license a description of "a role" of the nutrient that may mislead the consumer by omitting mention of a directly related, conflicting role. If Vitamin E's actual role is both to support and to harm heart health, depending on the dosage actually supplied, then a label on a product presented in the harmful dosage yet revealing only the former aspects of the vitamin's role relative to health is incomplete in a way that could be material to the consumer's exercise of choice in deciding whether to buy the product.

This conclusion finds textual support in section 321(n) of the FDCA, which provides that when evaluating whether an article (i.e., a product) is misbranded because the labeling[6] is misleading, we "shall" take into account, among other things,

> not only representations made or suggested by [the] statement . . . but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual.

[6] "Labeling," includes the product's "label," 21 U.S.C. § 321(m), which includes "written, printed, or graphic matter upon the immediate container of any article," id. § 321(k).

Id. § 321(n).

This statutory command that we consider the omission of material facts fits hand-in-glove with the mandate of section 343(r)(6)(B) that the seller's substantiation show that a health statement is both "truthful and not misleading." Id. § 343(r)(6)(B). More broadly, it aligns well with the FDA's stated mission to "promote," id. § 393(b)(1), and "protect the public health by ensuring that . . . [dietary supplements] are safe . . . and properly labeled," id. § 393(b)(2)(A). If a particular dietary supplement functions to harm health in the supplied or recommended dosage, a label claiming that the product supports health is plausibly viewed as misleading within the meaning of section 343(r)(6)(B). To rule otherwise would be to treat the FDCA as granting license to entice consumers to unwittingly incur risk and harm.

In so reasoning, we do not accept Kaufman's argument that evidence showing a supplement does not reduce heart disease necessarily implies that the nutrient itself has no function in maintaining heart health. On the contrary, Congress has expressly specified that sellers of dietary supplements can "describe[] the role of a nutrient . . . intended to affect the structure or function in humans," id. § 343(r)(6)(A), even while simultaneously disavowing any claim that the product is intended "to . . . prevent any disease," id. § 343(r)(6)(C). And the FDA has in turn

promulgated a regulation blessing terms like "promote," "maintain," and "support," so long as the seller has substantiation for the description. See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. at 1014. Thus, any nutrient or ingredient that, for example, the heart needs might be described as supporting heart health, even if taking the supplement form of the nutrient actually does nothing to improve the health of one's heart, as long as the claimed beneficial function is substantiated and the description of the nutrient's role is not misleadingly incomplete. And while Kaufman plausibly suggests that the drawing of such a distinction between the ingredient's function and its lack of any impact on morbidity likely tricks many consumers who unwittingly think that such a product will reduce the likelihood of poor heart health, this is a form of finesse that the statute and the regulations allow. See, id. (suggesting increased consumer "choice" as a reason for allowing such marketing). On the other hand, a section 343(r)(6) disclaimer, while legally sufficient to immunize a structure/function claim that is truthful and not misleading, does not immunize a structure/function claim for which the manufacture lacks the required substantiation or that misleadingly fails to disclose the harmful aspects of the nutrient's structure/function.

As we have already noted, we read the studies referenced in the complaint only to see if, on their face, they render implausible Kaufman's allegation that substantiation for CVS's heart health statements does not exist. CVS might have other studies that paint a different and more credible overall picture. Expert testimony might also shed a different light than that cast by the complaint or by a bare reading of the studies unaided by additional context. The point, simply, is that the cited studies do not on their face render implausible the allegation that CVS lacks substantiation that the "heart health" and "supports heart health" statements are truthful and not misleading descriptions of the function of Vitamin E supplements in humans. For purposes of Rule 12(b)(6), it therefore follows both that Kaufman has adequately pled that CVS's labeling of its Vitamin E supplement is not in keeping with the requirements of FDCA section 343(r), and that federal law does not, therefore, preempt application of New York state law for the purpose of holding CVS accountable for misleading consumers by failing to satisfy those requirements. With CVS advancing no argument that unsubstantiated and deceptive health claims made in marketing a consumer product are not actionable under New York law, we therefore reverse the dismissal of Kaufman's claim under NYCPA section 349.

### C. Unjust Enrichment

Kaufman's claim of unjust enrichment under New York law rests necessarily on her allegation that CVS's label was "deceptive." CVS correctly observes that if the label does not violate the FDCA's requirements, the unjust enrichment claim also necessarily fails. See Cleary v. Philip Morris, Inc., 656 F.3d 511, 517 (7th Cir. 2011) ("[I]f an unjust enrichment claim rests on the same improper conduct alleged in another claim, then the unjust enrichment claim will be tied to this related claim--and, of course, unjust enrichment will stand or fall with the related claim."). The district court agreed, and dismissed the unjust enrichment claim. Kaufman, 2016 WL 347324, at *8.

Given our finding that the complaint adequately alleges that the label's statements were misleading in a manner that violated the requirements of section 343(r), it follows that the unjust enrichment count is also not preempted to the extent that its reference to deceptive conduct is solely to the conduct that would render the label misleading under section 343(r). CVS offers no other grounds for dismissing the unjust enrichment count. We therefore reverse the dismissal of that count for all the reasons set forth concerning the NYCPA section 349 count.

## III. Conclusion

The district court's dismissal of Kaufman's complaint is reversed.