23-642-cv

United States Court of Appeals for the Second Circuit

Theda Jackson-Mau, on behalf of herself and others similarly situated,
Plaintiff-Appellant,

vs.

Walgreen Co. and **International Vitamin Corporation,**
Defendants-Appellees.

On Appeal from a Judgment of the United States District Court
Eastern District of New York No. 1:18-cv-4868-FB-VSM
The Honorable Frederic Block

APPELLEES' ANSWERING BRIEF

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FRAP 26.1 DISCLOSURE STATEMENT

Defendant-Appellee Walgreen Co. is a wholly owned subsidiary of Walgreens Boots Alliance, Inc., a holding company incorporated in Delaware that has issued shares to the public, which are listed on NASDAQ (WBA). No publicly held corporation owns 10% or more of WBA's stock.

Defendant-Appellee International Vitamin Corporation's parent corporation is American Vitamin Corporation. No publicly held corporation owns 10% or more of its stock.

Dated: January 5, 2024

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APPELLEES' ANSWERING BRIEF

I. INTRODUCTION

This is the fourth lawsuit making the same mislabeling allegations regarding defendant-appellee International Vitamin Corporation's ("IVC") glucosamine sulfate products, with all three prior cases having been resolved favorably for IVC.[1] In this

[1] *Parker v. Wal-Mart Stores, Inc.*, was dismissed for failure to state a claim. 367 F. Supp. 3d 979, 984 (E.D. Mo. 2019). *Amavizca*

case, plaintiff-appellant Theda Jackson-Mau filed suit for monetary damages under New York law against both IVC (the manufacturer) and defendant-appellee Walgreen Co. d/b/a Walgreens (the retailer for whom IVC manufactured the Finest Nutrition Glucosamine Sulfate that plaintiff purchased) (collectively, "defendants"). Plaintiff claimed that the product was mislabeled, and therefore misbranded under the federal Food, Drug and Cosmetic Act ("FDCA"), because the product allegedly was not single-crystal glucosamine sulfate potassium chloride but instead a blend of glucosamine hydrochloride and potassium sulfate.

The FDCA, as amended by the Dietary Supplement Health and Education Act of 1994 and the Nutritional Labeling and Education Act and implemented by FDA regulations, specifies how the chemical composition of a dietary supplement must be verified and how such verified ingredients must be declared on

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v. Nutra Manufacturing, LLC, was resolved for nuisance value after the district court ruled that the case could not proceed as a class action. No. 8:20-cv-01324-RGK-MAA, 2021 WL 4945242 (C.D. Cal. June 15, 2021). And in *Hollins v. Walmart Inc.*, the district court entered summary judgment in favor of IVC and the other defendant, No. 2:19-cv-05526-SVW, 2021 WL 3748315 (C.D. Cal. Aug. 17, 2021) ("*Hollins I*"), and the Ninth Circuit affirmed in a published decision, 67 F.4th 1011 (9th Cir. 2023) ("*Hollins II*").

the product's label. In particular, FDA regulations permit supplement ingredients to be verified using the methods given in the Official Methods of Analysis of the Association of Official Analytical Chemists International ("AOAC") or, if no AOAC method is available or appropriate, by other reliable and appropriate methods. FDA regulations also specify that a so-verified supplement ingredient be declared on the product's label according to its "common or usual name" as given in an official pharmacopoeial source. State-law claims that would require deviation from these regulatory requirements are preempted by the FDCA.

The district court properly found that plaintiff's claims were preempted because her experts conceded that the product meets the federally accepted United States Pharmacopeia ("USP") identity test for glucosamine sulfate potassium chloride and matches the European Pharmacopeia ("EP") certified reference standard for that product.[2] The district court also properly found that plaintiff's claims were alternatively preempted because the sampling and testing methods that

[2] Under the FDCA, the USP is considered an "official compendium." 21 U.S.C. § 321(j). The EP "is a compendial standard recognized in the European Union and observed by the United States." *Hollins II*, 67 F.4th at 1016.

plaintiff's experts used to attempt to contradict validated USP and EP compendial test methods did not comply with FDA regulations governing supplement testing. Finally, with respect to preemption, the district court properly found that plaintiff's challenge to defendants' use of glucosamine sulfate potassium chloride on not only the product's nutrition panel—the familiar panel on the back of any food product marketed for individual sale that lists calories, ingredients, and other scientific information—but also as the product's name, did not preclude a finding of preemption because FDA regulations permit a dietary supplement to be named according to its ingredients and the only active ingredient in the product as determined consistently with FDA regulations was glucosamine sulfate potassium chloride.

II. JURISDICTIONAL STATEMENT

The district court's jurisdiction rested on 28 U.S.C. §§ 1332(d)(2) and 1367. This Court's jurisdiction rests on 28 U.S.C. § 1291.

The district court entered its order granting summary judgment for defendants on January 24, 2023, and judgment on January 25, 2023. SA 13, 35.[3]

[3] "SA" refers to the Joint Special Appendix, and "JA" to the Deferred Joint Appendix.

Plaintiff timely moved for reconsideration (*see* JA1438) of that order on February 7, 2023, *see* Fed. R. Civ. P. 59(e), which the district court denied on April 4, 2023 (SA36).

Plaintiff noticed her appeal on April 17, 2023. JA1443. The notice was timely. *See* Fed. R. App. P. 4(a)(1)(A) & (a)(4)(A)(iv); *see also Banister v. Davis*, 140 S. Ct. 1698, 1703 (2020).

III. ISSUES PRESENTED & STANDARD OF REVIEW

1. Whether the district court correctly found plaintiff's challenges to the Finest Nutrition Glucosamine Sulfate label preempted.

2. Whether the district court properly granted, in the alternative, summary judgment for defendants on the merits of plaintiff's New York General Business Law § 349 claim.

Each of these issues is reviewed *de novo*. *See Buono v. Tyco Fire Prods., LP*, 78 F.4th 490, 496 (2d Cir. 2023) (preemption); *Dish Network Corp. v. Ace Am. Ins. Co.*, 21 F.4th 207, 212 (2d Cir. 2021) (summary judgment).

IV. BACKGROUND

A. Statutory and Regulatory Background

1. The FDCA's Preemption and Misbranding Provisions

In passing the FDCA, Congress charged the Food and Drug Administration ("FDA") with "protect[ing] the public

health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). In 1990, Congress amended the FDCA with the Nutrition Labeling and Education Act ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (1990), which established both "the circumstances under which claims may be made about nutrients in foods" and dietary supplements and "uniform national standards for the nutritional claims and the required nutrient information" displayed on food and supplement labels. H.R. Rep. No. 101-538, at 7, 12 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337, 3342; *see also* 21 U.S.C. § 321(ff) ("a dietary supplement shall be deemed to be a food within the meaning of this chapter").[4]

To ensure that its "uniform national standards" would not be undermined by state and/or local action, the NLEA also added to the FDCA an express preemption provision:

> (a) [N]o State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—
>
> ***

[4] In 1994, Congress amended the FDCA yet again when it enacted the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417, 108 Stat. 4325 (1994), which provides the FDA with regulatory authority over dietary supplements.

> (3) any requirement for the labeling of food of the type required by section 343(b) . . . of this title [requiring that the food not be offered under the name of another food] that is not identical to the requirement of such section . . . ,
>
> (4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title [requiring certain nutrition information to be on the food's label.]

21 U.S.C. § 343-1(a)(3), (4);[5] *see also* 21 C.F.R. § 100.1(c)(4) (defining "not identical to" as a state-law requirement that "directly or indirectly imposes obligations or contains provisions . . . that . . . [a]re not imposed by or contained in the applicable provision (including any implementing regulation)" of the FDCA).

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[5] The statute preempts both statutory and common law duties that are not identical to federal requirements. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992) ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law" because "'[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief.'" (citation omitted)). Accordingly, "private plaintiffs may bring only actions to enforce violations of '*state laws* imposing requirements identical to those contained in the FDCA.'" *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 808 (9th Cir. 2020) (citation omitted).

The FDCA prohibits the "misbranding of any food," including dietary supplements. 21 U.S.C. § 331(b). Section 343 lists various circumstances under which a food will be "deemed to be misbranded." 21 U.S.C. § 343. The misbranding prohibitions implicated by plaintiff's challenge to the district court's ruling are:

- Section 343(b): "offer[ing]" a food "for sale under the name of another food";
- Section 343(q): using a "label or labeling" that does not "bear[] [various] nutrition information" required by subsection 343(q) and 21 C.F.R. §§ 101.36 & 101.9(g); and
- Section 343(s)(2)(A)(i): "fail[ing] to list the name of each ingredient of the supplement."

Section 343(q) includes a subsection specific to the nutrition information that dietary supplements must provide and states:

> A dietary supplement product . . . shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the [U.S. Food and Drug Administration ("FDA")] which shall provide that—
>
> (i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has

> been established by the Secretary . . . and shall list any other dietary ingredient present and identified as having no such recommendation;
>
> (ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving.

21 U.S.C. § 343(q)(5)(F)(i) & (ii).

2. Regulations Requiring Supplement Ingredients To Be Identified by Their "Common or Usual Name"

Pursuant to section 343(q), the FDA promulgated regulations governing the nutrition labeling of dietary supplements at 21 C.F.R. § 101.36. Under these regulations, dietary ingredients such as glucosamine sulfate potassium chloride, for which the FDA has not established a Reference Daily Intake ("RDI") or Daily Reference Value ("DRV"), are governed by 21 C.F.R. § 101.36(b)(3), which provides that such dietary ingredients "shall be declared by their common or usual name." *Id.* at § 101.36(b)(3)(i). Additionally, "[t]he quantitative amount by weight per serving of other dietary ingredients shall be presented in the same manner as the corresponding information required in paragraph (b)(2)(ii) of this section." *Id.*at § 101.36(b)(3)(ii). Compliance with this "common or usual name" requirement is determined in accordance with specified testing protocols, described below.

3. Regulations Requiring that Label Compliance Testing Be Performed Using an AOAC or "Other Reliable" Method

In 21 C.F.R. § 101.36, the FDA also specified how compliance with section 101.36(b)(3)'s "common or usual name" requirement must be determined:

> Compliance with this section will be determined in accordance with § 101.9(g)(1) through (g)(8), (g)(10), and (g)(11), except that the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot.

21 C.F.R. § 101.36(f)(1). Thus, to establish that a dietary supplement is misbranded under the FDCA, testing must be conducted on a randomly selected sample of 12 consumer packages, or 10 percent of the packages from the lot at issue, whichever is smaller.

Under 21 C.F.R. § 101.9(g)(2)—one of the sections referenced in § 101.36(f)(1)—these selected packages "shall be analyzed by appropriate methods as given in the 'Official Methods of Analysis of the AOAC International,' or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures."[6]

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[6] The AOAC Official Methods of Analysis are "a comprehensive collection of chemical and microbiological

The FDA's *Compliance Program Guidance Manual* for dietary supplements explains that supplement manufacturers should analyze their products "by methods contained in the AOAC, USP, FDA Foods Program Compendium of Analytical Laboratory Methods, or National Formulary, as applicable and appropriate." FDA, *Compliance Program Guidance Manual, Program 7321.008: Dietary Supplements—Foreign and Domestic Inspections, Sampling, and Imports* (Sept. 30, 2020), at 24, *available at* https://www.fda.gov/media/116340/download (hereinafter "*FDA Compliance Program Guidance Manual*"). It goes on to emphasize that "[u]se of methods contained in one of" the above compendia "*must take precedence over the use of other methods*." *Id.* (emphasis added). Thus, as the FDA has explained, if a "dietary ingredient is covered by an official compendium," like the USP and EP, "FDA would expect that the dietary ingredient's common or usual name to be drawn from that source." 60 Fed. Reg. 67194, 67201 (Dec. 28, 1995).

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methods of analysis" which "have undergone rigorous scientific review and validation to determine the performance characteristics for the intended analytical application and fitness for purpose." 81 Fed. Reg. 33742, 33748-49 (May 27, 2016).

B. Plaintiff, Her Purchase, and Her Claims

Plaintiff is a New York consumer who alleged that she purchased a bottle of defendants' Finest Nutrition Glucosamine Sulfate at a Brooklyn Walgreens store in 2018 "for her joint pain." JA16, 19-20.[7] Plaintiff further alleged that she purchased this particular product because she, like "[m]any consumers," "believe[s] that Glucosamine Sulfate [i]s more effective than Glucosamine Hydrochloride." JA14, 17-18, 19-20. Plaintiff had never before purchased a glucosamine supplement. JA1368-69.

After purchasing the product, plaintiff discussed it with her friend, lead counsel Carl Stine. JA1370. Her conversation with Mr. Stine "led her to believe" the product might be "fake." *Id*. She "brought the pills from the bottle she purchased to her counsel, who then sent the contents to a laboratory for analysis." JA20. According to the complaint, "[t]he lab's report concluded that the pills contain Glucosamine Hydrochloride, and did not detect the presence of Glucosamine Sulfate." *Id.*

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[7] This brief discusses plaintiff's amended complaint. Her original complaint was against only Walgreens and also included an unjust enrichment claim. JA1-13. After the district court dismissed the unjust enrichment claim (SA6) (which plaintiff does not challenge here on appeal), she amended her complaint to add IVC as a defendant on her Section 349 claim (JA25-26); *see also* SA9, 12 (granting permission to so amend).

Plaintiff further alleged that "products containing Glucosamine Sulfate are more expensive than those with Glucosamine Hydrochloride," that "she would not have purchased the product" if she had known that "it did not contain Glucosamine Sulfate," but that she "would purchase [the product] again if she could be sure that the bottle actually contain[ed]" Glucosamine Sulfate. JA14, 20-21. However, plaintiff has never alleged the product caused her any kind of illness or physical injury, or even that it was ineffective.

On behalf of herself and a putative class, plaintiff sued defendants Walgreens and International Vitamin Corporation for a violation of New York General Business Law ("GBL") § 349's prohibition on deceptive business practices (first and third causes of action), claiming that she and the putative class "purchased a product and received less than what was promised" and are "entitled to receive an amount necessary to fulfill their expectation[s]." JA24, 26. Plaintiff also sued Walgreens for breach of contract (second cause of action), claiming that she and the putative class "received a product with less value than the amount paid" and that they are entitled to reimbursement of "the amounts paid for" the product. JA25.

C. Procedural History

1. The Summary Judgment Order

The district court granted summary judgment for defendants, finding that "the FDCA preempts all of [plaintiff's] claims, and that her [GBL] Claim would fail on the merits in any event." SA15.

With respect to preemption, the district court first held that plaintiff's challenges to defendants' listing of glucosamine sulfate potassium chloride on the nutrition panel are expressly preempted by section 343-1(a)(3) & (4) of the FDCA. SA24. The district court so held because: (1) 21 C.F.R. § 101.36(b)(3)(i) requires that dietary ingredients for which RDIs and DRVs have not been established—like glucosamine sulfate potassium chloride—be described "by their common or usual name," which is drawn from official compendia like the United States Pharmacopeia or European Pharmacopeia; and (2) defendants' product "complies with USP and EP specifications for glucosamine sulfate potassium chloride." SA23 (citing 60 Fed. Reg. at 67201). In so holding, the district court rejected plaintiff's assertion that the USP and EP methods were inappropriate because they were the result of a "testing loophole" that failed to distinguish between single-crystal glucosamine sulfate and a blend of glucosamine hydrochloride and potassium sulfate (the

latter being what plaintiff asserted the product to actually contain). SA24. As the district court remarked, criticisms regarding the appropriateness or efficacy of compendial methods are not properly directed to "the courts" through litigation. *Id.* Instead, such criticisms must be directed to the entities that promulgated the compendial methods—namely, the USP or EP—who might be willing to "refin[e]" them, or to the FDA, since it "chooses to rely on" them. SA24-25 (quoting *Hollins I*, 2021 WL 3748315, at *4).

With respect to the nutrition panel, the district court alternatively held that plaintiff's challenges were expressly preempted because 21 C.F.R. § 101.36(f)(1) and 21 C.F.R. §§ 101.9(g)(1)-(g)(8), (g)(10, and (g)(11) "set out an elaborate sampling and testing process to be followed by plaintiffs challenging labels of dietary supplements" and plaintiff "fail[ed] to comply with [those] sampling and testing requirements." SA29, 30.

The district court also rejected plaintiff's challenges to defendants' use of "Glucosamine Sulfate" as the name of the product on the front of the label, finding those challenges to be "barred by conflict preemption." SA26. The district court explained that 21 U.S.C. § 343(s)(2)(B) expressly permits manufacturers and distributors to market a product "as a

'dietary supplement' and nothing more" *or* "with the name of . . . an ingredient" taken from the "supplement facts" (or nutrition) panel. SA26-27. Although "[s]ection 343(s)(2)(B) . . . is not given express preemptive power," "the regulations governing the names of ingredients provided on the 'supplement facts' panel" from which the front label may be derived "are given preemptive effect." SA27. The district court explained that, because the upshot of plaintiff's claims is that the product be renamed "glucosamine hydrochloride" and because *that* "ingredient name . . . is rightfully not listed on the 'supplement facts' panel," a judgment in plaintiff's favor "would violate § 343(s)(2)(B)," which renders her challenges to the product's name conflict preempted. SA27-28.

Finally, "because these preemption issues are novel in the Second Circuit," the district court went on to address plaintiff's GBL deceptive-practices claim on its merits and alternatively found that this claim failed because plaintiff failed "to adduce evidence of . . . a cognizable injury." SA31-34.[8] Specifically, the district court first acknowledged that plaintiff did "not allege having suffered any bodily injury" from using the product "or that it lacked any advertised efficacy." SA33. Under New York

[8] Defendants did not challenge plaintiff's breach-of-contract claim on its merits.

law, the district court observed, that left plaintiff with only the ability to establish injury by showing that she "paid a premium price" due to the alleged deception. *Id.* But after evaluating plaintiffs' evidence, the court concluded that she failed to create a triable issue over whether blended glucosamine is worthless (which, if shown, could have established a price premium) or whether there is a "discernable comparative pricing trend between supplements containing the glucosamine blend and single-crystal glucosamine" (which also could have established a price premium). SA34.

2. Denial of Plaintiff's Motion for Reconsideration

Following entry of judgment for defendants, plaintiff moved for reconsideration under Federal Rule of Civil Procedure 59(e) and E.D.N.Y. Local Rule 6.3, taking issue with three of the district court's findings in its summary judgment order: (1) that the product passes validated compendial test methods for the identification of glucosamine sulfate potassium chloride; (2) that plaintiff failed to comply with sampling and testing requirements under 21 C.F.R. § 101.9(g)(2) and 21 C.F.R. § 101.36; and (3) that, with respect to the merits of plaintiff's GBL claim, there is consumer demand for supplements containing a

glucosamine blend. JA1438-42. The district court denied the motion. SA36.

With respect to compendial methods, plaintiff asserted that she had not conceded that "the Product complies with USP and EP specifications for glucosamine sulfate potassium chloride" and that the USP monograph actually requires glucosamine to be in single-crystal form. JA1439-41. The district court rejected this assertion as a basis for reconsideration, holding: (1) that the court never tagged plaintiff with such a concession; (2) that plaintiff's expert, Dr. Neil Spingarn, admitted in his deposition that blended glucosamine sulfate "'will meet the specifications of the USP identity test'"; and (3) that, in any event, the dispute that plaintiff had manufactured with respect to the compendial methods "amounted to a criticism of the compendial sources, not a genuine issue of fact as to whether the Product complied with them." SA37-39 & n.1.

With respect to the court's previous finding that plaintiff's challenges to the nutrition panel were preempted because she failed to comply with the federal regulations' sampling and testing requirements, the court held that "this finding had no effect on the Court's grant of summary judgment, as the Order had already held that claims regarding the supplement facts panel were expressly preempted by other labeling

requirements"—namely, the requirement that primary ingredients be listed according to what the official compendia say they are, and the product here passed the validated USP and EP compendial tests for the identification of glucosamine sulfate potassium chloride. SA39.

Finally, the court rejected plaintiff's reprised assertion with respect to the merits of her GBL claim that "there is 'no consumer demand for supplements containing the glucosamine blend'" of glucosamine hydrochloride and potassium sulfate—*i.e.,* that it is worthless. JA1441. The court noted the inconsistency in plaintiff's position, insofar as Dr. Spingarn testified that, in his view, "every" glucosamine supplement on the market is such a "blend." SA40. Additionally, the court noted that the "only evidence" to support plaintiff's argument was testimony from defendants' market-value expert, Dr. Jesse David, who had actually given unrebutted testimony that there "*is* market demand for glucosamine hydrochloride." *Id.* (emphasis added).

V. SUMMARY OF ARGUMENT

Plaintiff's mislabeling claims fail for a simple reason: FDA regulations promulgated to enforce the FDCA provide that dietary supplement manufacturers must use validated compendial identification methods that do not distinguish

between the single-crystal and blended forms of glucosamine sulfate potassium chloride. Plaintiff and her expert disagree with the FDA's regulatory choices, but because the FDCA expressly preempts state-law mislabeling claims that are "not identical to" FDCA standards, plaintiff's disagreement with the regulations cannot save her claims. 21 U.S.C. § 343-1(a)(3), (4); 21 C.F.R. § 100.1. Moreover, even if plaintiff's claims were not preempted, they would fail as a matter of New York law because plaintiff has presented no evidence to show that defendants' alleged misbranding caused her any injury.

First, to the extent plaintiff's claims are based on the term "glucosamine sulfate potassium chloride" in the product's nutrition panel, they are preempted by 21 U.S.C. § 343(q) and applicable FDA regulations. Under those regulations, dietary ingredients listed on the nutrition panel must be identified "by their common or usual name." 21 C.F.R. § 101.36(b)(3)(i). "Compliance with this 'common or usual name' requirement is determined in accordance with specified testing protocols." *Hollins II*, 67 F.4th at 1014-15. Plaintiff's claims are preempted at the outset because her experts conceded that defendants' product meets the federally accepted USP identity test for glucosamine sulfate potassium chloride and matches the EP certified reference standard for that product. Plaintiff's claims

are additionally preempted because her experts: (1) failed to conduct any testing using the FDA-endorsed identity testing methods set out in the official AOAC International, USP, and EP compendia; (2) failed to test an adequate sample of the product; and (3) relied on made-for-litigation methodologies that are neither "reliable" nor "appropriate" for the identification of glucosamine sulfate potassium chloride. *See* 21 C.F.R. § 101.9(g)(2). Any one of these failures is fatal to plaintiff's misbranding claim.

Second, plaintiff suggests that defendants could be liable for using the common or usual name of the single active dietary ingredient on the product's label even though the FDCA *requires* the use of that name in the product's nutrition panel. This theory both defies common sense and conflicts with the plain text of 21 U.S.C. § 343(s)(2)(B), which explicitly states that a dietary supplement's label must "identify the product by using the term 'dietary supplement', *which term may be modified with the name of such an ingredient*" listed in the nutrition panel. 21 U.S.C. § 343(s)(2)(B) (emphasis added). The Ninth Circuit has already rejected this exact theory of liability, *see Hollins II*, 67 F.4th at 1022, and this Court should decline plaintiff's invitation to create a circuit split.

Third, plaintiff's New York GBL claims fail as a matter of state law even if they are not preempted. As the district court correctly held, New York law requires that plaintiff show she suffered some injury beyond merely having purchased the product. Plaintiff argues that she suffered an injury because she paid more for the product than she otherwise would have. The record, however, establishes that plaintiff failed to provide any evidence that she paid a price premium for the supplement. Accordingly, plaintiff's GBL claims were properly dismissed.

This Court should affirm.

VI. ARGUMENT

Plaintiff's mislabeling claims are completely preempted by the FDCA. Insofar as they relate to statements made in the nutrition panel, plaintiff's mislabeling claims are preempted by section 343(q) because they would require calling the product's sole active ingredient by something other than its "common and usual name." Plaintiff's experts conceded that the product meets the identity specifications for glucosamine sulfate set out in the official, FDA-endorsed USP and EP compendia. Plaintiff's expert also conceded that the product matched the EP's certified reference standard for glucosamine sulfate potassium chloride. Plaintiff's competing identity testing did not comply with the sampling process set out in the regulations or use the FDA-

mandated AOAC method applicable to glucosamine sulfate supplements. And the alternative testing methods relied on by plaintiff's experts were neither reliable nor appropriate as required by the FDA. With respect to the front of the label, the district court correctly recognized that any reading of section 343(b) that imposes liability for calling a supplement by the name of its sole active ingredient necessarily conflicts with the plain text of section 343(s)(2)(B).

Moreover, even if plaintiff's claims were not preempted by the FDCA, the district court was correct in recognizing that plaintiff's state law claims fail because she suffered no injury.

A. Plaintiff's Mislabeling Claims Are Preempted Because the Product Is Glucosamine Sulfate Potassium Chloride According to FDA-Endorsed USP and EP Compendial Sources

The FDA adopted 21 C.F.R. § 101.36(b)(3)(i) to implement 21 U.S.C. § 343(q)'s nutrition information labeling requirements. *See* § 343(q)(5)(F). Under 21 C.F.R. § 101.36(b)(3)(i), dietary ingredients like glucosamine sulfate potassium chloride "shall be declared by their common or usual name when they are present in a dietary supplement." And when a "dietary ingredient is covered by an official compendium," the FDA expects "the dietary ingredient's common or usual name to be drawn from that source." 60 Fed. Reg. at 67201; *see also Hollins II*,

67 F.4th at 1019 (quoting regulation). Because it is undisputed that the USP and EP provide validated test methods for the identification of glucosamine sulfate potassium chloride and plaintiff's experts agree that defendants' product meets those specifications, this Court's inquiry should end there.

The crux of plaintiff's appeal is that those reference standards and identification procedures are somehow wrong. But such an "allegation is irrelevant for purposes of determining what federal law requires." *Hollins II*, 67 F.4th at 1019. As multiple courts have explained, a plaintiff's disagreement with the scientific accuracy of the compendia is best resolved through agency action or via scientific dialogue with the pharmacopoeiae, not the courts. *See, e.g.*, *Hollins I*, 2021 WL 3748315, at *4 ("[I]t is not this Court's role to second guess the scientific and technical judgment of the FDA."). The question is whether the product meets the definition of "glucosamine sulfate potassium chloride" provided in these compendia. Because plaintiff has not established otherwise through appropriate methodologies (as set forth below), her claim that the product is mislabeled is preempted as a matter of federal law.

1. FDA Regulations Incorporate Validated Compendial Identification Methods

For over a century, federal food and drug labeling regulations have incorporated official compendia to determine whether a product is mislabeled. *See* Pure Food and Drug Act of 1906, Pub. L. No. 59-384, §§ 1, 2, 7, 34 Stat. 768 (repealed 1938) (prohibiting the sale of a drug "under or by a name recognized in the United States Pharmacopoeia [if] . . . it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopoeia"); 21 U.S.C. § 343(s)(2)(D), (E) (incorporating official compendia in misbranding regulations for dietary supplements). Thus, when a "dietary ingredient is covered by an official compendium," the FDA expects "the dietary ingredient's common or usual name to be drawn from that source." 60 Fed. Reg. at 67201; *see also Hollins II*, 67 F.4th at 1019 (quoting regulation).

Plaintiff contends that the FDA does not defer to USP or EP naming or testing methodologies, but this fundamentally misunderstands the role of official compendia in the regulatory scheme. Br. 24-32. As the Ninth Circuit, the district court in this case, and another district court all have already recognized, the USP and EP identity specifications for glucosamine sulfate potassium chloride are *regulatory* definitions. *Hollins I*, 2021 WL 3748315 at *4; *Hollins II*, 67 F.4th at 1019; SA24. By way of

analogy, compendial identification methods and reference standards for "glucosamine sulfate potassium chloride" are like the dictionary definitions of "graham cracker" cited by the court in *Warren v. Stop & Shop Supermarket, LLC*, 592 F. Supp. 3d 268, 280 (S.D.N.Y. 2022). The compendia define the "common or usual name" of a dietary ingredient for purposes of 21 C.F.R. § 101.36(b)(3)(i).

Furthermore, plaintiff is simply wrong that the FDA gives "precedence" to "common usage" over compendial sources. Br. 23-27. The FDA's *Compliance Program Guidance Manual* for dietary supplements explains the "methodology" to be used when reviewing supplement labels "for conformance with 21 CFR [§§] 101.9, 101.36 and other applicable labeling requirements." *FDA Compliance Program Guidance Manual*, *supra*, at 23 (citations as in original). The FDA states that supplement manufacturers should:

> Analyze the composite by methods contained in the AOAC, USP, FDA Foods Program Compendium of Analytical Laboratory Methods, or National Formulary, as applicable and appropriate. *Use of methods contained in one of these compendiums must take precedence over use of other methods.*

Id. at 24 (emphasis added); *see also* 72 Fed. Reg. 34752, 34853 (June 25, 2007) (reiterating to manufacturers that "you may use

validated methods that can be found in official references, such as AOAC International, USP, and others").

Even plaintiff's experts agree that the compendia provide the regulatory definition for glucosamine sulfate potassium chloride. Plaintiff's expert Dr. Spingarn conceded during the *Hollins* litigation "that the FDA requires the use of a compendial test method to validate a labeling claim," *Hollins II*, 67 F.4th at 1018, and his colleague at S&N Labs has previously observed that the EP's definition of glucosamine sulfate is "a regulatory definition." JA1385. Dr. Glen Jackson also agreed that "FDA permits dietary supplement manufacturers to rely on the validated USP test methods to identify dietary ingredients." JA1435. This is consistent with the opinion of Dr. Darryl Sullivan, an expert for defendants, who explained that, "[i]f a material meets USP specifications for an ingredient, it is, by regulatory definition, properly identified as that ingredient on the product label." JA52.

2. Official USP and EP Identification Tests Show the Product Is Glucosamine Sulfate Potassium Chloride

Plaintiff's own expert, Dr. Spingarn, conceded that the product both passes the validated USP identity tests for glucosamine sulfate potassium chloride and matches the EP's certified reference standard for glucosamine sulfate potassium

chloride. Specifically, Dr. Spingarn agreed that defendants' product has "passed the USP monograph[']s identity test for glucosamine sulfate potassium chloride" and admitted that both the blended and single-crystal forms of glucosamine sulfate "will pass the USP identity tests." JA121-22. Dr. Spingarn also concluded that defendants' product matches EP's certified reference standard for glucosamine sulfate potassium chloride. JA1383. IVC's own testing confirmed that the product passes the USP identity test for glucosamine sulfate potassium chloride. JA1405.

Plaintiff raises several arguments to avoid the conclusions that inevitably follow from these concessions, but none of them has merit.

First, plaintiff claims the USP identification test has a "blind spot" because the USP's chemical formula for "glucosamine sulfate potassium chloride" uses a dot (indicating single crystal glucosamine sulfate) instead of a plus symbol (which indicates a blend). Br. 35. But it is the USP's *identification procedure* that matters for regulatory purposes. Under the heading "identification," the USP sets out a four-part procedure for identifying "glucosamine sulfate potassium chloride." JA177-78. Plaintiff admits that these tests, if used to analyze defendants' product, indicate that it is in fact glucosamine sulfate potassium

chloride. Br. 30. While plaintiff claims this is evidence of a "blind spot" in the procedure (Br. 35-39),[9] it is far more likely (as discussed below) that the USP does not distinguish between the single-crystal and blended forms of glucosamine sulfate potassium chloride because the distinction is irrelevant.

Second, plaintiff cites a boilerplate disclaimer on the EP reference standard's Origin of Goods document to claim that the EP's certified reference standard should be ignored. Br. 39-41. But taken in context, the disclaimer cited by plaintiff is obviously a reference to the fact that the EP standard is for laboratory use rather than human consumption. Immediately following the "no other purpose" sentence cited by plaintiff, the document states the standard is "intended solely for laboratory testing in vitro" and is "NOT FOR FOOD. NOT FOR HUMAN

[9] Plaintiff's effort to frame Dr. Klibanov's testimony as suggesting that the composition of the product is evidence of fraud is misleading. In fact, Dr. Klibanov was agreeing with a hypothetical posed by plaintiff's counsel, and agreed only that, *if* someone attempted to maliciously defeat the USP testing procedure, they may be able to do so. JA744-45. But Dr. Klibanov also pointed out that this would be "tricky to do" (JA254) because "the results of some of the other tests may not conform to the USP compendia characteristics" (JA744-45), and most importantly, that is "not what happened" here (JA254).

CONSUMPTION." JA841. The paragraph immediately prior to the sentence cited by plaintiff reads:

> The European Pharmacopoeia is the official intergovernmental body responsible for establishment of quality standards for medicines in Europe. *Compliance with the standards is mandatory for any medicine to be sold in Europe.* In many cases, to test compliance, pharmaceutical manufacturers have to use a reference substance.

Id. (emphasis added). This document only confirms that, as with the USP identity testing procedure, the EP's certified reference standard is a *regulatory* standard.

Finally, plaintiff asserts that IVC's test results are not admissible under Rule 56(c)(2) because they have not been authenticated. Br. 50-52. This assertion is incorrect as a matter of law because defendants have witnesses who "could . . . authenticate[]" these documents "at trial." JA1404; *see Jacobs v. New York City Dep't of Educ.*, 768 F. App'x 86, 87 n.1 (2d Cir. 2019) (unauthenticated documents may be considered on summary judgment if they could be authenticated at trial) (summary order); *Am. Ref-Fuel Co. of Niagara, LP v. Gensimore Trucking, Inc.*, No. 02-CV-814C(F), 2007 WL 2743449, at *3 n.3 (W.D.N.Y. Sept. 18, 2007) (same). Moreover, it is a moot point given that the plaintiff's own expert conceded that the product passes verified USP and EP identification tests for glucosamine sulfate

potassium chloride. Plaintiff's belief that the FDA, USP, and EP have all erred in deciding that "glucosamine sulfate potassium chloride" is the common or usual name for a blend of glucosamine hydrochloride and potassium sulfate is insufficient to overcome federal preemption—her remedy is to raise that issue with the FDA and scientific authorities.[10]

B. Plaintiff's Mislabeling Claims Are Also Preempted Because They Rely on Identity Testing Procedures that Are Not "Identical" to Those Specified by the FDA

Beyond incorporating validated compendial identification methods, the FDA regulations also specify the exact testing protocol used to determine whether a supplement's label complies with federal law. 21 C.F.R. § 101.36(f). First, with exceptions not relevant here, the sample for analysis "shall

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[10] In fact, Dr. Spingarn contacted the USP and EP years ago to insist that they had erred in defining "glucosamine sulfate potassium chloride." A USP scientist expressed an interest in reviewing Dr. Spingarn's data, but the record does not reflect any change to the USP standard. JA959-60; JA149. The EP flatly informed Dr. Spingarn that glucosamine sulfate potassium chloride "is prepared from glucosamine hydrochloride isolated from natural sources . . . and potassium sulfate" and explained there is no "specification requiring that the material is a co-crystal." JA317. This information prompted Dr. Spingarn's colleague, Dr. French, to observe that the EP's monograph was "a regulatory definition and not a chemical definition." JA319.

consist of a composite of 12 subsamples (consumer packages) or 10 percent of the number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot." 21 C.F.R. § 101.36(f)(1). Second, dietary supplements "shall be analyzed by appropriate methods as given in the 'Official Methods of Analysis of the AOAC International.'" 21 C.F.R. § 101.9(g)(2). Finally, even when a non-compendial method is allowed, section 101.9(g)(2) requires the use of a "reliable and appropriate" identification procedure. Because the testing upon which plaintiff's claims rely indisputably fails to meet any of these requirements, her claims are preempted.

1. Plaintiff Did Not Randomly Test Twelve Samples From the Same Inspection Lot

Plaintiff has acknowledged that the bottle of glucosamine sulfate at issue in this case bears a label stating it came from "Lot 000005." JA1369. To comply with federal regulations, plaintiff had to test at least twelve randomly selected, representative samples from that same consumer lot. *See* 21 C.F.R. § 101.36(f)(1). She conceded that she has not done so. JA1370. Plaintiff's expert tested only one bottle from Lot 000005, and plaintiff does not even possess twelve samples of the product from Lot 000005. JA1370-71.

Allowing a plaintiff to rely on testing performed on lots other than those they purchased and claim are mislabeled conflicts with the FDA's requirement that label compliance be determined on a lot-by-lot basis. As the FDA has explained:

> One comment strongly recommended that FDA address sampling issues. It suggested that the current procedure in § 101.9(e)(2) (and in proposed § 101.9(g)(2)) of preparing a composite of 12 subsamples taken from a single lot be changed. Instead, it was suggested that a sample composite for analysis represent 12 different lots.
>
> The agency disagrees with the suggested change in sampling procedures. The comment's suggestion reflects a sampling objective that appears to focus on estimating the nutrient content of product for a specified quantity (*e.g.*, a company's production). *FDA's sampling objective is to determine whether the average, within a given lot (a quantity that is defined in current § 101.9(e)(1)), meets label claims.* From a compliance evaluation standpoint, the suggested sampling scheme is not a feasible alternative because the results obtained would not be traceable to a specific lot should an overage or deficiency be encountered.

58 Fed. Reg. 2079, 2162 (Jan. 6, 1993) (emphasis added); *see also FDA Compliance Program Guidance Manual*, *supra*, at 23 ("Do not perform nutrient analyses on samples containing more than one manufacturing lot code.").

The FDA's rule exists for a reason. As Dr. Sullivan explained, dietary supplement manufacturers (including IVC) routinely source raw materials from different companies, and different lots of bulk tablets are manufactured separately using different lots of raw materials. JA57. This means that "the results of testing on one lot of a dietary supplement may be affected by variances in the raw materials used or in the manufacturing process." *Id*. Because "[f]actors that could have altered the nutrient content of one lot may not be present for subsequent lots," and thus "results obtained from . . . one lot . . . cannot be translated to other lots," the FDA has decided that label compliance must be determined on a lot-by-lot basis. 58 Fed. Reg. at 2163. Plaintiff's admitted failure to follow this testing mandate is fatal to her claim that the product is mislabeled.

2. Plaintiff Failed to Use the AOAC Official Method for Testing Glucosamine Sulfate Supplements

Under 21 C.F.R. § 101.9(g)(2), dietary supplements "shall be analyzed by appropriate methods as given in the 'Official Methods of Analysis of the AOAC International.'" Other methods may not be used unless the AOAC method is not "available or appropriate." *Id*. Plaintiff concedes that an official AOAC method exists for testing glucosamine sulfate supplements, and admits that Dr. Spingarn failed to use the

official AOAC method. Br. 32, 43. Plaintiff's sole argument is that the FDA-mandated AOAC method is not "appropriate" because it does not specifically test for single-crystal glucosamine sulfate. Br. 32-35. Plaintiff's disagreement with FDA's regulatory choices cannot overcome federal preemption.[11]

AOAC Official Method 2005.01 is "[a]pplicable to the analysis of glucosamine in raw materials *and dietary supplements containing glucosamine sulfate and/or glucosamine hydrochloride*." JA60 (emphasis added). Official Method 2005.01 determines the amount of glucosamine freebase in dietary supplements, which then can be converted to determine the amount of glucosamine sulfate in a dietary supplement. JA1367. It also includes a formula for calculating the percentage of glucosamine sulfate in dietary supplements and a formula for calculating the amount of glucosamine sulfate per product unit. *Id*. Simply put, AOAC Official Method 2005.01 must be used to determine whether a glucosamine sulfate supplement complies with FDA labeling requirements. Because plaintiff admits that she did not use

[11] Contrary to plaintiff's claim (Br. 34 n.23), defendants have never conceded that the AOAC Official Method is inappropriate. Defendants specifically argued in district court that use of the AOAC Official Method is mandatory. JA216-18, 232-33.

Official Method 2005.01 when testing the product, her claims are preempted. Br. 43; JA1370.

Nonetheless, plaintiff insists the AOAC method is not "appropriate," but this argument is foreclosed by the plain text of 21 C.F.R. § 101.9(g)(2). That subsection explicitly states that "appropriate methods" are "given in the 'Official Methods of Analysis of the AOAC International.'" In other words, the AOAC's Official Methods of Analysis *are* the FDA testing standard,[12] and the AOAC manual determines whether an AOAC method is "appropriate." *See* FDA, *Guidance for Industry FDA Nutrition Labeling Manual—A Guide for Developing and Using Databases*, 1998 WL 34327548, at *15 (Mar. 1998) ("Alternative methodology is recommended only in the *absence* of AOAC Official Methods." (emphasis added)). Official Method 2005.01 plainly states that it applies to "dietary supplements containing glucosamine sulfate." JA60. It is therefore the "appropriate method . . . given in the 'Official Methods of Analysis of the AOAC International'" to determine whether a glucosamine

[12] FDA has repeatedly explained that section 101.9(g)(2) incorporates the Official Methods of Analysis of AOAC International by reference. 81 Fed. Reg. at 33960; 79 Fed. Reg. 11880, 11956 (Mar. 3, 2014); 58 Fed. Reg. at 2183.

sulfate supplement meets FDA labeling requirements. 21 C.F.R. § 101.9(g)(2).

Contrary to plaintiff's argument, the FDA has already determined that AOAC Official Method 2005.01 is "suitable to achieve the purpose for which it is used." Br. 35 (quoting 58 Fed. Reg. at 2110). Under section 101.9(g)(2), non-AOAC methods used must be "reliable and appropriate" (*i.e.*, validated) but AOAC methods need only be "available or appropriate." The regulation cited by plaintiff applies only when no AOAC method exists. *See* 58 Fed. Reg. at 2110. This makes perfect sense: the FDA already knows that AOAC methods have been validated for their intended uses, and so deems them reliable for regulatory purposes. *See* FDA, *Guidance for Industry Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Small Entity Compliance Guide*, 2010 WL 5574459, at *30 (Dec. 2010) ("Validated methods can be found in official references, such as AOAC International.") (hereinafter "*FDA Guidance for Industry Current Good Manufacturing Practice*").

Even if the appropriateness of Official Method 2005.01 could be challenged via third-party testing, plaintiff simply has

the science wrong.[13] As Dr. Sullivan explained in his declaration, the AOAC method is appropriate for testing a finished supplement product regardless whether it specifically identifies single-crystal glucosamine sulfate because manufacturers are independently required to identify the raw materials in a supplement. JA654-56. Notably, Dr. Sullivan was part of the team that performed validation studies on Official Method 2005.01 prior to its adoption by the AOAC and the FDA, and his work is cited in FDA guidance to the supplement industry. *See* JA653; FDA, *Guidance for Industry FDA Nutrition Labeling Manual—A Guide for Developing and Using Databases*, 1998 WL 34327548, at *15 (describing Dr. Sullivan's work as a "reference[] of particular usefulness"). Finally, the validation studies conducted using Official Method 2005.01 specifically included tests on 1000-milligram glucosamine sulfate tablets—the exact

[13] Even if Official Method 2005.01's appropriateness presents a question of fact, that question is properly resolved by the courts at the summary judgment phase because, as the Supreme Court recently clarified, "a judge, not the jury, must decide the pre-emption question" even if doing so requires resolving "contested brute facts." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676, 1680 (2019) (addressing FDCA preemption); *see also id.* at 1680 ("In this context, that 'better positioned' decisionmaker is the judge.").

product at issue in this case.[14] Those validation studies, conducted by researchers at twelve different laboratories, concluded that AOAC Official Method 2005.01 was "rugged and robust." JA74.

The FDA and AOAC have good reasons for selecting a testing methodology that does not distinguish single-crystal glucosamine sulfate. As Dr. Klibanov explained in his expert report and plaintiff has conceded, single-crystal glucosamine sulfate and a glucosamine sulfate blend have the exact same ions in the exact same ratios. JA185-87. Upon ingestion, both forms dissociate into exactly the same ions, meaning that any structural difference is immaterial. JA1386-87. Nor is it clear that a better test for single-crystal glucosamine sulfate even exists—plaintiff's expert, Dr. Spingarn, has never been able to detect it using his methods. JA1385-86.

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[14] *See* Joseph ZiQi Zhou, et. al., *Single Laboratory Validation of a Method for Determination of Glucosamine Sulfate and/or Glucosamine Hydrochloride by High-Performance Liquid Chromatography with FMOC-Su Derivization*, 87 J. AOAC Int'l 1083, 1086 (2004) (*available at* JA76); Joseph ZiQi Zhou et. al., *Determination of Glucosamine in Raw Materials and Dietary Supplements Containing Glucosamine Sulfate and/or Glucosamine Hydrochloride by High-Performance Liquid Chromatography with FMOC-Su Derivization: Collaborative Study*, 88 J. AOAC Int'l 1048, 1049 (2005) (*available at* JA64).

For purposes of preemption, it accordingly does not matter if AOAC Official Method 2005.01 does not specifically identify single-crystal glucosamine sulfate. If plaintiff believes the identity testing standards adopted by the FDA are imprecise, she is free to raise this issue with AOAC International or bring it to the FDA's attention via the administrative rulemaking process. This Court, however, "is not the proper forum to resolve [plaintiff's] definitional dispute with FDA and the scientific community." *Hollins I*, 2021 WL 3748315, at *5. Plaintiff's admitted failure to use the AOAC method means her mislabeling claims seek to hold defendants to a standard which is "not identical" to the regulations, and they are therefore preempted. 21 U.S.C. § 343-1(a)(3), (4).

3. The Testing Conducted by Dr. Spingarn Would Not Be a Reliable or Appropriate Alternative Under FDA Regulations in Any Event

Even if the federally required USP, EP, and AOAC testing methods did not control the outcome of this case, plaintiff would still have to use "reliable and appropriate analytical procedures" to establish that defendants' product is mislabeled. 21 C.F.R. § 101.9(g)(2). Yet in *Hollins I*, the Central District of California rejected a virtually identical misbranding claim because Dr. Spingarn's methods for identifying single-crystal glucosamine

sulfate are not reliable or appropriate. 2021 WL 3748315, at *1. The *Hollins I* court concluded that Dr. Spingarn's methods for identifying single-crystal glucosamine sulfate—Scanning Electron Microscopy with Energy-Dispersive X-Ray Analysis ("SEM-EDX"), X-Ray Diffraction ("XRD"), and Fourier Transform Infrared Spectroscopy ("FTIR")—are not reliable because they are not validated, not peer reviewed, not published, and have never been tested for accuracy using a certified reference standard of glucosamine sulfate potassium chloride. *Id*. at *3-4.[15]

Nothing has changed since *Hollins* was decided. Dr. Spingarn is still relying on the same made-for-litigation methods he used in *Hollins*, and his expert report in this case relies on the work he did in *Hollins*. JA1375. Dr. Spingarn's methods are still unreliable because they are not validated, do not incorporate a certified reference standard to ensure accuracy, and have not been published in a peer-reviewed journal. Accordingly, plaintiff's claims are preempted even if the regulations do allow for the use of alternative testing methods.

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[15] The *Hollins I* court also found that Dr. Spingarn was "not credible" because he lied in his deposition and a sworn declaration. 2021 WL 3748315, at *1-2.

a. Dr. Spingarn's Methods Are Not Validated

Non-compendial methods require "appropriate validation," *Hollins II*, 67 F.4th at 1015 (quoting 58 Fed. Reg. at 2109); *see also FDA Compliance Program Guidance Manual*, *supra*, at 24 ("If AOAC, USP, or National Formulary methods are not available, then use of an appropriate validated method from the scientific literature or from in-house work is appropriate."). Validated methods are those that are shown to be "appropriate for their intended use." 21 C.F.R. § 111.320(a); *see also* FDA, *Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products* (3d ed. 2019), at 4. Validation testing must "include *at a minimum* evaluation of the following performance characteristics: sensitivity, selectivity, false positive rate, false negative rate . . . , minimum detectable concentration, ruggedness, and confirmation of identity." *Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products*, at 7 (emphasis added).

Dr. Spingarn admitted during the *Hollins* litigation that his methods for identifying single-crystal glucosamine sulfate—SEM-EDX, XRD, and FTIR—have never been validated for that

purpose.[16] *Hollins I*, 2021 WL 3748315, at *2-3. Justifiably concerned over the *Hollins I* court's rejection of his methods as unreliable, Dr. Spingarn went back and "validated" his methods *after* he had performed the product testing on which plaintiff's claims rely. JA55. Moreover, as Dr. Sullivan and Dr. Derek Beauchamp pointed out, Dr. Spingarn's *post hoc* validation does not even purport to demonstrate that his methods are capable of distinguishing between single-crystal glucosamine sulfate potassium chloride and a glucosamine sulfate blend. JA56; JA293. Thus, there is no evidence that Dr. Spingarn's methods are "appropriate for their intended use." 21 C.F.R. § 111.320(a).

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[16] Plaintiff argues that courts accept these methods as valid "for a variety of substances." Br. 43 n.29. But every court considering Dr. Spingarn's use of them as a method to identify *glucosamine sulfate potassium chloride* has rejected them as inappropriate for that purpose. *See Hollins I*, 2021 WL 3748315, at *2 ("Spingarn's testing methods are not reliable and appropriate."); *Hollins II*, 67 F.4th at 1019 (holding Spingarn's methods are impermissible because they differ from the requirements imposed by section 101.9(g)(2) and 21 U.S.C. § 343(q)); SPA30 ("Jackson-Mau's claims . . . are therefore additionally expressly preempted by her failure to comply with sampling and testing requirements."). Even Judge Wardlaw, dissenting from the panel decision in *Hollins II*, agreed that Dr. Spingarn's methods were not reliable or appropriate. *See* 67 F.4th at 1022-23 (Wardlaw, J., dissenting in part).

Additionally, when deposed in this case regarding his methods, Dr. Spingarn testified that he had never evaluated his methods for basic performance characteristics:

- He did not "need to do a quantitative measurement of sensitivity" for his methods. JA164.
- A "numeric value" for the selectivity of his methods "has not been reported." JA165-66.
- He has "not reported" a "false positive rate." JA166.
- The false negative rate for his methods "is zero" because he thinks there are "no false negatives" in his data. JA167.

These performance characteristics are the "minimum" required for method validation. *Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products*, at 7. Because Dr. Spingarn's methods still are not validated for the identification of single-crystal glucosamine sulfate, they are not reliable or appropriate as required by 21 C.F.R. § 101.9(g)(2). JA1374.

b. Dr. Spingarn's Methods Do Not Incorporate a Certified Reference Standard

The reliability "of a particular testing method depends, at least in part, on whether that method incorporates certified reference standards." *Hollins I*, 2021 WL 3748315, at *4 (citing

FDA publications). Reference standards are samples of a material, sold by EP, USP, or another source, that are certified to be an authentic sample of that material. JA49. The FDA "recommend[s]" that identity testing "use compendia reference standards whenever possible." 72 Fed. Reg. at 34893. As mentioned, the EP provides a certified reference standard for "glucosamine sulfate potassium chloride" and Dr. Spingarn conceded that the product matches that standard. JA312; JA1383.

After Dr. Spingarn tested the EP's certified reference standard using his own methods, however, he concluded that it too was not "real" single-crystal glucosamine sulfate. JA955. In fact, Dr. Spingarn has never once detected what he considers "real" (*i.e.*, single-crystal) glucosamine sulfate potassium chloride using his methods and believes that the single-crystal substance does not exist.[17] JA956; JA173. As the *Hollins I* court observed, Dr. Spingarn's insistence that courts should ignore an FDA-endorsed, authoritative, and certified reference standard is simply more evidence that his methods are unreliable and that his disagreement with the FDA-approved methods is

[17] Notably, even if Dr. Spingarn were correct that single-crystal glucosamine sulfate does not exist, defendants' product still would not be mislabeled because "glucosamine sulfate potassium chloride" and "glucosamine sulfate" would be the common or usual name of the ingredient at issue.

definitional and regulatory rather than scientific. 2021 WL 3748315, at *4.

c. Dr. Spingarn's Methods Have Never Been Published or Peer Reviewed

Alternative methods must be "scientifically valid," which generally means that they are "based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research." *FDA Guidance for Industry Current Good Manufacturing Practice*, *supra*, 2010 WL 5574459, at *30. No published scientific work supports Dr. Spingarn's use of SEM-EDX, XRD, and FTIR to identify single-crystal glucosamine sulfate potassium chloride. As the *Hollins I* court correctly concluded, the fact that Dr. Spingarn's made-for-litigation methods have never been published or peer reviewed both "raise[s] serious *Daubert* concerns" and suggests that they are not reliable and appropriate for purposes of the FDA's regulations. 2021 WL 3748315, at *3.

d. No Other Expert Has Replicated Dr. Spingarn's Results

Perhaps because Dr. Spingarn's methods for identifying single-crystal glucosamine sulfate have been rejected as unreliable by every judge to consider them, plaintiff repeatedly cites Dr. Glen Jackson's opinions in an effort to persuade this Court that Dr. Spingarn's methods are reliable. But Dr. Jackson

performed no testing and relied entirely on the flawed testing performed by Dr. Spingarn in forming his opinions. JA1375. Given that he conducted no testing of his own, Dr. Jackson's opinion does not change the fact that Dr. Spingarn's methods lack validation, fail to incorporate a reference standard, are not published or peer reviewed, and are therefore unreliable under section 101.9(g)(2).

Plaintiff cites Dr. Jackson's opinion that FTIR, SEM-EDX, and XRD are "common, published, and validated methods of analysis . . . for the characterization of pharmaceuticals in their native, solid state." Br. 43 (quoting JA517). But Dr. Jackson admitted that there is no published scientific literature supporting Dr. Spingarn's use of the SEM-EDX method to identify glucosamine sulfate. JA521. Moreover, validation is "the process of demonstrating or confirming that a method is suitable *for its intended purpose*." *Guidelines for the Validation of Chemical Methods in Food, Feed, Cosmetics, and Veterinary Products* at 4 (emphasis added). Even if a method is validated for the identification of *some pharmaceutical,* that does not mean it is also validated to identify single-crystal glucosamine sulfate potassium chloride.

Plaintiff also claims that Dr. Beauchamp "obtained the same results" as Dr. Spingarn when testing the product using the

XRD method, but is careful to omit the context of that result. Dr. Beauchamp explained that the XRD method relies on a library database which "does not include a reference standard for glucosamine sulfate potassium chloride." JA292. Accordingly, "XRD testing properly performed on a reference standard of Glucosamine Sulfate Potassium Chloride . . . will incorrectly identify the substance as Glucosamine Chloride and Potassium Sulfate." *Id.*. Ultimately, Dr. Beauchamp's report unequivocally stated that "XRD is not a valid methodology to distinguish between glucosamine sulfate potassium chloride and glucosamine hydrochloride with potassium sulfate." *Id*.

C. Plaintiff's Claims Based on the Front of the Label Fail Because They Require the Product To Be Identified by Something Other Than Its "Common and Usual Name"

Plaintiff contends that her claims are not preempted because they do more than just challenge the use of "glucosamine sulfate potassium chloride" on the nutrition panel; they challenge the name of the product itself. Br. 20. Because manufacturers and retailers are required to use the common and usual name throughout the product as a whole, plaintiff's distinction is not one of any legal significance. The essence of plaintiff's claim is that section 343(b) should be read to prohibit conduct which is required by subsection 343(q) and expressly

permitted by subsection 343(s). But as the Ninth Circuit held, it is a "common-sense conclusion" that using the "'common or usual name' of a product to identify the product on the label does not constitute offering that product for sale 'under the name of another food,' in violation of § 343(b)." *Hollins II*, 67 F.4th at 1020. Because plaintiff cites no authority to disrupt this "common-sense conclusion," this Court—as the *Hollins II* majority correctly did—should reject plaintiff's argument because it fails both as matter of law and logic.

1. Glucosamine Sulfate and Glucosamine Sulfate Potassium Chloride Are "Common or Usual" Names for the Product

As discussed, the product must identify all ingredients by their "common or usual name" as determined by federal testing requirements for purposes of the nutrition panel. But plaintiff argues that even if her claims relating to names used on the nutrition panel are preempted by section 343(q), her claims relating to the front of the label escape preemption by operation of 21 U.S.C. § 343(b) (requiring that a food not be offered under the name of another food). Br. 22. "Logically, using the 'common or usual' name of a product to identify the product on the label does not constitute offering that product for sale 'under the name of another food,' in violation of § 343(b)." *Hollins II*, 67 F.4th at 1020. Indeed, subsection (s) requires the label to "identify the

product by using the term 'dietary supplement', *which term may be modified with the name of such an ingredient*" listed in the nutrition panel. 21 U.S.C. § 343(s)(2)(B) (emphasis added). In other words, if the dietary ingredient listed in the nutrition panel is listed by its "common or usual" name, the scheme permits the use of the "common or usual" name elsewhere on the label. *See Hawkins v. Kroger Co.*, 906 F.3d 763, 770 (9th Cir. 2018) (recognizing that, "if FDA regulations *expressly permit* the claim . . . on the face of a product's packaging, any state law claim to the contrary would be preempted" (emphasis added)); *see also Durnford v. MusclePharm Corp.*, 907 F.3d 595, 603 (9th Cir. 2018) ("[A] state-law misbranding claim that would permit a state to impose requirements . . . different from those *permitted* under the FDCA—is preempted" (emphasis added)).

Still, plaintiff points to 21 C.F.R. §§ 101.3 and 102.5 as evidence that even if subsection (s) has preemptive force (it does), it "does not override" the broader prohibition that products cannot be sold under the name of another food. Br. 22, 24-26. This argument is without merit. The regulation cited by plaintiff regarding statements of identity discusses the need to read the statute "as a whole" because the agency was explaining why it adopted 21 C.F.R. § 101.3(g). *See* 60 Fed. Reg. at 67194-96. The FDA explained that Congress enacted section 343(s)(2)(B) in

1994 as part of the DSHEA. *See* note 4, *supra*. That statute added the aforementioned requirement that dietary supplement labels "identify the product by using the term 'dietary supplement,' which term may be modified with the name of such an ingredient." 60 Fed. Reg. at 67195. The regulation cited by the plaintiff simply explains that the agency adopted 21 C.F.R. § 101.3(g) to clarify that supplement labels must include the phrase "dietary supplement." *Id.* at 67196 ("For the foregoing reasons, FDA is proposing to add § 101.3(g), which states that products marketed as dietary supplements shall bear the term 'dietary supplement' as part of their statement of identity.").

In fact, section 101.3 explicitly clarifies that a supplement's statement of identity may be taken from the name of a dietary ingredient that satisfies 21 U.S.C. § 343(q). It provides that a dietary supplement's "principal display panel"[18] must include "a statement of . . . identity." 21 C.F.R. § 101.3(a). Furthermore, section 101.3(g) explicitly states that a dietary supplement:

> shall be identified by the term "dietary supplement" as a part of the statement of identity, except that the word "dietary" *may be deleted and replaced by the name*

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[18] The "principal display panel" is "the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale." 21 C.F.R. § 101.1.

> *of the dietary ingredients in the product* (*e.g.*, calcium supplement).

(emphasis added). Dietary ingredients, in turn, "shall be declared by their common or usual name when they are present in a dietary supplement." 21 C.F.R. § 101.36(b)(3)(i). And the FDA was explicit about the fact that a dietary ingredient's "common or usual name" adopted pursuant to section 101.36(b)(3)(i) should be drawn from an official compendium:

> The agency is proposing in § 101.36(b)(3)(i) that other dietary ingredients be listed by their common or usual name. . . . To the extent that another dietary ingredient is covered by an official compendium, FDA would expect that the dietary ingredient's common or usual name to be drawn from that source.

60 Fed. Reg. at 67201 (citation omitted).

Plaintiff's efforts to obfuscate notwithstanding, the statute, regulations, and FDA guidance are all consistent. Because 21 U.S.C. § 343(s)(2)(B) explicitly permits the labeling of a dietary supplement with the name of a dietary ingredient, that label cannot violate subsection (b) if the ingredient's name complies with the testing and labeling regulations established by subsection (q). Regulations adopted pursuant to subsection (q) state that a dietary ingredient's common or usual name should be drawn from an official compendium. *See* 21 C.F.R.

§ 101.36(b)(3)(i), (f)(1); 60 Fed. Reg. at 67201. Thus, when a dietary supplement is labeled with the name of its sole ingredient, the supplement's name and "statement of identity" are drawn from the same source as the "common or usual name" of its active ingredient: official USP and EP compendia. And because those compendial sources require both the single-crystal and blended varieties to be called "glucosamine sulfate potassium chloride," "under federal law, glucosamine sulfate *or* glucosamine sulfate potassium chloride are common or usual names for the blended formulation of glucosamine sulfate." *Hollins II*, 67 F.4th at 1020 (emphasis added).[19]

2. Plaintiff's Reliance on the *Hollins II* Dissent Is Misplaced

Plaintiff resists these "common-sense conclusion[s]" and instead urges this Court to adopt the *Hollins II* dissent. Br. 20 n.16. This Court should decline that invitation to create a split with the Ninth Circuit. As the *Hollins II* majority correctly explained, the dissent's theory that "federal testing requirements do not apply to the label outside of the nutrition panel" was based on a misreading of the Ninth Circuit's prior decision in *Durnford* and first principles of FDCA preemption. *Compare* 67

[19] Plaintiff has never alleged that there is any meaningful difference between "glucosamine sulfate" and "glucosamine sulfate potassium chloride." *See* Br. 2.

F.4th at 1020-21 (majority op.) *with id.* at 1022 (Wardlaw, J. dissenting). Properly interpreted, *Durnford* is in harmony with both *Hollins II* and this case.

In *Durnford*, the Ninth Circuit was confronted with two supplement mislabeling claims: (1) a claim that the product declared an inaccurate *amount* of protein per serving on the nutrition panel, and (2) a claim that the product inaccurately reported the *source* of that protein on both the front label and below the required nutrition information in the nutrition panel. *Id.* at 598-99.

The Ninth Circuit found that the first claim was preempted by FDA regulations because "disclosure of the amount of protein content on the nutrition panel is required by statute, and the proper means of calculating that amount is set out in the regulation," "even if" the resulting calculation is "misleading." *Id.* at 599, 602; *see also id.* at 602 (because the FDCA "require[d] the disclosure of the 'amount' of 'total protein'" a certain way, and because "regulations have the same preemptive effect as a statute," "the possibility of liability under state law" was "foreclose[d]"). But the court reversed on the second claim because, unlike the first, there were no regulations explaining how the manufacturer should represent the *source* of the protein

on the product label.[20] *Id.* at 603-04. Rather, those representations were gratuitous marketing statements that neither the FDCA nor FDA regulations expressly permitted. As such, the challenge to them was not preempted. *Compare Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 484-85 (7th Cir. 2020) (FDCA labeling requirements will not immunize "*voluntarily add*[*ed*] deceptive content that is *not required* by [other] federal [labeling requirements]" (emphasis added)) *with Durnford*, 907 F.3d at 603 ("[A] state-law misbranding claim . . . that would permit a state to impose requirements . . . different from those *permitted* under the FDCA—is preempted" (emphasis added)) *and Hawkins*, 906 F.3d at 770 ("[I]f FDA regulations *expressly permit* the claim . . . on the face of a product's packaging, any state law claim to the contrary would be preempted" (emphasis added)).

Because this case deals with only label representations that are governed by FDA regulations, plaintiff's claims are

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[20] *Hollins II* confirmed that *Durnford* was controlling only as to "the distinction between the label's information about the *amount* of protein and the *source* of the protein" and that *Durnford* "did not put any weight on the location of the information." *Hollins II*, 67 F.4th at 1020 n.9.

preempted as to both the nutrition panel and the front of the label.[21]

D. Alternatively, the Court Should Affirm the Grant of Summary Judgment on Plaintiff's Deceptive Practices Claim Because She Did Not Prove a Cognizable Injury

Even if this Court does not agree that the district court properly dismissed plaintiff's action on preemption grounds, it should still affirm the district court's dismissal of plaintiff's deceptive business practices claim under New York law.

1. New York Law Requires Plaintiff Demonstrate She Suffered an Injury Apart from Merely Purchasing the Product

While this Court must view the evidence in the light most favorable to plaintiff, she still must present evidence on every

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[21] Plaintiff's reliance on *Reid v. Johnson & Johnson*, 780 F.3d 952, 960 (9th Cir. 2015), for the proposition that a "requirement to state certain facts in the nutrition label is not a license to make that statement elsewhere on the product" fares no better than her flawed reliance on *Durnford*. Br. 22 n.17. Like in *Durnford*, in *Reid*, there was an FDA requirement to include a misleading declaration in the nutrition panel—a requirement that the amount of trans fat be rounded down to zero grams notwithstanding that the product actually contained trans fat. *See* 780 F.3d at 955, 960. Although any challenge to that declaration would have been preempted, the plaintiff's challenge to the manufacturer's gratuitous "No Trans Fat" declaration elsewhere on the product was not because no FDA regulation permitted it. *See id.* at 962-63.

element of her claim. To succeed on a New York GBL § 349 claim, this means plaintiff had to present evidence showing that "(1) the act or practice was consumer-oriented; (2) the act or practice was misleading in a material respect; and (3) the plaintiff was injured as a result." *Spagnola v. Chubb Corp.*, 574 F.3d 64, 74 (2d Cir. 2009).

Plaintiff here failed on the third element: she failed to provide any evidence that she was injured by the allegedly misleading acts as a matter of New York law. It is well established that "[a]lthough a monetary loss is a sufficient injury to satisfy the requirement under § 349, that loss must be independent of the loss caused by the alleged breach of contract." *Id.* In other words, plaintiff cannot state a § 349 claim on the theory that "consumers who buy a product that they would not have purchased, absent a manufacturer's deceptive commercial practices, have suffered an injury under General Business Law § 349." *Small v. Lorillard Tobacco Co.*, 720 N.E.2d 892, 898 (N.Y. 1999).

Plaintiff thus must show that she suffered a monetary injury beyond the fact that she would not have purchased defendants' product absent the allegedly misleading label. The primary manner in which New York courts have allowed a plaintiff to make such a showing is by demonstrating that they

paid more for the product than they otherwise would have—a price premium—absent the misleading act. *See id.* at 898 & n.5 (denying claim seeking solely "monetary recoupment of the purchase price" of the product but recognizing that "plaintiff might have a claim for the higher price the consumer paid for the product as a result of the misrepresentation").

2. Plaintiff Cannot Cite Any Evidence that She Paid a Price Premium for the Product

The district court here properly applied this principle in its decision granting summary judgment. First, it correctly recognized that plaintiff does not claim that she was bodily injured by the product. SA33. Because plaintiff's only alleged harm was monetary, she must present evidence that her harm exceeded the mere fact that she would not have purchased the product had she known that the product contained glucosamine hydrochloride, instead of glucosamine sulfate.

Plaintiff failed to retain a damages expert to testify regarding product pricing. Nevertheless, plaintiff argues that she could prove that she paid a "premium" price for the product here because, she claims, a supplement containing a glucosamine blend is inherently worthless, so paying for the product at all means she paid a premium. Br. 53. She claims that the product's worthlessness is established by the fact that no

supplement labeled as glucosamine blend is offered for sale. *Id.* The sole evidence plaintiff points to in support of this claim is that defendants purportedly "conceded" that there are no products on the market labeled as glucosamine hydrochloride blended with potassium sulfate. *Id.* (citing JA270). But plaintiff's citation does not support her claim. Rather, defendants specifically contested whether plaintiff's evidence on this point was admissible (it is not) and explained that plaintiff was misreading the cited material in claiming it meant a glucosamine blend is never sold under that label. JA270-71.

The record further demonstrates that plaintiff has not provided evidence that she paid a price premium for the supplement. For example, defendants asserted in the district court that it is undisputed that "Plaintiff has adduced no evidence that single-crystal glucosamine sulfate potassium chloride typically sells for a higher price in the marketplace than the blend of glucosamine sulfate potassium chloride does." JA1387. Plaintiff attempted to dispute this fact by stating "Potassium sulfate is most commonly sold as a fertilizer and there is no apparent market or consumer demand for a blend of glucosamine hydrochloride and potassium sulfate sold as a dietary supplement at any price," and pointing to excerpts from the deposition transcript of expert Dr. David. JA1388. But again,

the citations do not support plaintiff's claim. The cited testimony explains that "*if* there was no demand for the product at any price" there may be a price premium. JA1308-09 (emphasis added). Dr. David further testified that the market price of a product "*could*" be zero "*if* it contains a potentially toxic ingredient" or "*if* it contains an ingredient that consumers might consider disgusting." JA1310 (emphasis added). But this does not establish that glucosamine blend *is* such a product, as plaintiff's expert never opined that blended glucosamine sulfate contained a potentially toxic ingredient.[22]

The cases plaintiff cites do not support a different conclusion. First, *Eidelman v. Sun Products Corp.*, No. 21-1046-cv, 2022 WL 1929250 (2d Cir. June 6, 2022), is inapposite. Plaintiff cites the case for the proposition that "a price premium is but one recognized method of establishing injury under §§ 349 and 350 . . . and a plaintiff need not allege a price premium in every case under these statutes" because "there is no such rigid 'price premium' doctrine under New York law." Br. 54. But *Eidelman*

[22] Plaintiff's attempt to portray potassium sulfate as a toxic or disgusting agent is belied by the evidence that potassium sulfate has common uses that are widely found in our diet. *See* JA1423. Indeed, FDA regulations explain that potassium sulfate "occurs naturally" and explicitly state that it may be used as a flavoring agent in food products. 21 C.F.R. § 184.1643.

did apply the price premium theory and held that the plaintiff there did not establish injury as a matter of law. *Eidelman* thus supports the district court's conclusion here. *See Eidelman*, 2022 WL 1929250, at *1-2.

Orlander v. Staples, Inc., 802 F.3d 289 (2d Cir. 2015), also supports the district court's conclusion. In that case, this Court compared Staples' misleading communications regarding the warranty services it would provide specifically to the price premium theory used for consumable goods. This Court held that Staples' failure to provide the services promised was similar to a consumer paying a price premium for a product because in both instances a consumer "purchased a product and did not receive the full value of her purchase." *Id.* at 302. But the Court did not suggest that the well-established price premium theory does not apply to consumable goods cases. Rather, its holding reinforces that whether a consumer paid a higher price for a product is the correct analysis in evaluating consumer injury.[23]

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[23] Plaintiff also cites *Lambert v. Nutraceutical Corp.*, 870 F.3d 1170, 1183 (9th Cir. 2017), *rev'd*, 139 S. Ct. 710 (2019) to support her claim that she suffered injury under GBL § 349. But that case addresses claims under an entirely different statutory scheme. The court there addressed claims under California consumer protection laws, and did not address injury under New York law.

Because plaintiff has failed to meet her burden to show an injury from defendants' allegedly deceptive practices, she is not entitled to statutory damages under the GBL. *See de Lacour v. Colgate-Palmolive Co.*, 338 F.R.D. 324, 344 n.10 (S.D.N.Y. 2021) ("[P]laintiffs must prove "actual . . . harm" in order to obtain statutory damages pursuant to GBL Section 349."). Thus, even if this Court does not agree with the district court's conclusion that plaintiff's claims can be dismissed on preemption grounds, it should nonetheless affirm the district court's dismissal of plaintiff's section 349 claim.

VII. CONCLUSION

The district court properly concluded that plaintiff's claims were preempted by federal law. This Court should affirm.

Dated: January 5, 2024

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of the Federal Rule of Appellate Procedure 32(a)(7)(B) and contains **12,473** words, exclusive of the corporate disclosure statement, the table of contents, the table of authorities, as counted by the Microsoft Word word-processing program used to generate this brief.

I certify that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word word-processing program with a 14-point Palatino font.

Dated: January 5, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on **January 5, 2024**, I electronically filed the foregoing document and accompanying appendices with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/Jean-Claude André