UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

EDWIN SEGOVIA and JUNIOR HERMIDA, on behalf of themselves and all others similarly situated, Plaintiffs, v. VITAMIN SHOPPE, INC., Defendant.	Case No. 14-cv-07061-NSR

DEFENDANT VITAMIN SHOPPE, INC.'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF MOTION TO DISMISS

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PRELIMINARY STATEMENT

Plaintiffs' opposition confirms there are no facts to support the utterly speculative conclusion that Vitamin Shoppe failed to disclose on its BodyTech product-line labels that the Products provide only a "fraction" of the purported "clinically-proven effective doses" of the active ingredient Aminogen®. The purported basis for this conclusion is a scientific study, yet the study neither identified a "clinically-proven effective dose" of Aminogen®, nor tested any of the BodyTech Products. Instead, the study concluded that Aminogen®, in fact, increased the absorption rate of processed whey protein concentrate ("WPC") as measured by statistically significant increases, a finding which absolutely confirms the truth and accuracy of the BodyTech labels' general structure/function claims—"Aminogen® . . . may help aid in the absorption and digestion of protein." Cases directly on point demonstrate that such "under-dosing" or extrapolation theories of "falsity" are meritless. And, Plaintiffs' opposition concedes that their "lactase claim" is premised upon no more than a tortured misinterpretation of the Whey Tech Pro 24 label. Therefore, dismissal of the Complaint in its entirety is required.

POINT I

THE COMPLAINT FAILS TO PLEAD THAT VITAMIN SHOPPE'S STATEMENTS ARE FALSE OR MISLEADING.

A. Plaintiffs' Conclusory Under-Dosing Contentions Are Thinly-Veiled Lack of Substantiation Claims.

It is well-settled that the labels on dietary supplements may bear statements that describe the role of a nutrient or ingredient intended to affect the structure or function in the human body, or characterize the documented mechanism by which a nutrient or ingredient acts to maintain such structure or function. *See* Dietary Supplement Health and Education Act of 1994 ("DSHEA"); 21 C.F.R. § 101.93(f) (permitting such "structure/function" claims). Consistent with DSHEA, the BodyTech protein supplements state that ***one of the ingredients***, a patented

enzyme cluster known as "Aminogen®": (i) "***may help aid*** in the absorption and digestion of protein," (Whey Tech Pro 24); (ii) "***helps your body*** breakdown and absorb protein" (100% Casein); and (iii) "***help[s] support*** amino acid absorption and nitrogen retention from whey protein" (Primal Pro™). *See* Declaration of Michael R. McDonald ("McDonald Decl.") Ex. C (emphasis added). The label for Whey Tech Pro 24 also states that it contains 25 mg of Aminogen® per serving. *Id.* Inasmuch as the FDA has exclusive jurisdiction over the safety and labeling of dietary supplements (particularly regarding a company's obligation to substantiate all product claims),[1] Plaintiffs concede that to plead a ***private*** cause of action challenging such structure/function claims, a complaint must sufficiently allege that the product claims are, in fact, false or misleading,[2] not simply that the claims lack scientific substantiation. *See* Pls.' Br. 6-8 n.12.

To establish "falsity," the Complaint relies exclusively on a single study of Aminogen®, the so-called "Absorption study," which concludes that Aminogen® supplementation in WPC supports an ***increased rate of protein absorption***. *See* Pls.' Br. 8; McDonald Decl. Ex. A. Clearly, though, Vitamin Shoppe's labels do not make any claims as to the ***rate or amount*** of protein absorbed, but simply state a ***fact***—*i.e.*, the patented grouping of enzymes known as Aminogen®, "***may help aid*** in the absorption and digestion of protein," McDonald Decl. Ex. C (emphasis added); in fact, that is what protein-digesting enzymes do, *see* Moving Br. 9.

Additionally, Plaintiffs' "falsity" claim incorrectly assumes that the "Absorption study" established "clinically-proven effective doses" for Aminogen® in dietary supplements, and thus,

[1] *See, e.g.*, Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/ucm073200.htm. The FTC has primary jurisdiction over advertising dietary supplements.

[2] Plaintiffs do not dispute the literal truth, *i.e.*, (i) Aminogen® "may help aid in the absorption and digestion of protein," "helps . . . breakdown and absorb protein"; (ii) Whey Tech Pro 24 contains 25 mg of Aminogen®.

they assert that lesser doses used in the BodyTech Products render the Products ineffective. Fundamentally, Plaintiffs claim that because a greater amount of Aminogen® was used in the "Absorption study" (to achieve *specified rates* of protein absorption), Vitamin Shoppe's claim that 25 mg of Aminogen® "***may help aid*** in the absorption and digestion of protein," McDonald Decl. Exs. A, C, must be false because there is no scientific support for this "dosage." As discussed more fully *infra*, Point I.B, just because one study found a particular dosage to be effective does not mean that a lesser dosage will be ineffective. Regardless, whether Plaintiffs' claims are poorly-disguised "lack of prior substantiation" claims, or general claims that the statements on the BodyTech labels have been "disproven" by scientific evidence, the result is the same because the "Absorption study" does not disprove any of Vitamin Shoppe's statements.

B. Plaintiffs Cannot Distinguish Directly Applicable Authority in Which the Same Under-Dosing Contentions Were Flatly Rejected.

Even assuming *arguendo* that there is more to Plaintiffs' theory than a lack of prior substantiation, the Complaint must be dismissed for the same reasons that other courts have dismissed other attempts to allege the same implausible claims. First, Plaintiffs cannot meaningfully distinguish *Hodges v. Vitamin Shoppe*, No. 13-3381, 2014 U.S. Dist. LEXIS 5109 (D.N.J. Jan. 15, 2014). *See* Moving Br. 11-13. *Hodges* soundly rejected virtually identical "under-dosing" allegations based upon studies that examined a product at higher dosages. 2014 U.S. Dist. LEXIS 5109, at *11. The *Hodges* court explained that this under-dosing theory required the court to make an extraordinary inferential "leap . . . made through nothing but speculation" to "bridge the studies cited to the conclusion underpinning the alleged falsity." *Id.* at *13. *Hodges* held that "[t]he implication that affirmative proof as to the effectiveness of an ingredient at one dosage renders it ineffective at some other, lower dose, as contained in the Product's formulation does not state a *prima facie* Consumer Fraud Act claim." *Id.*; *see also*

Gaul v. Bayer Healthcare LLC, No. 12-5110, 2013 U.S. Dist. LEXIS 22637, at *4-8 (D.N.J. Feb. 11, 2013) (determining that even if a research study supporting manufacturer's label claims was found "unreliable," it would be "too great a leap" to conclude that the label claims were false because the study was not "probative of the falseness" of the label claims).

Here, the Court should likewise reject Plaintiffs' "leap" based on rank speculation to "bridge" the "Absorption study" to the baseless conclusion that the dosage of Aminogen® in the BodyTech Products is ineffective. Merely because one study finds one particular dosing amount effective for a specified absorption rate, does not mean that a lesser amount will render that product completely unable to "***help aid*** in the absorption and digestion of protein." McDonald Decl. Ex. C. Plaintiffs' claims about Aminogen® are improperly based on that ***same exact*** inferential theory. Not surprisingly, Plaintiffs cannot credibly distinguish *Hodges*.[3]

Second, Plaintiffs' Complaint requires dismissal for the same reasons expressed in *Eckler v. Wal-Mart Stores, Inc.*, 2012 U.S. Dist. LEXIS 157132 (S.D. Cal. Nov. 1, 2012). *See* Moving Br. 11. In *Eckler*, the plaintiff claimed that the dietary supplement Equate Glucosamine MSM ("Equate") did not deliver the promised benefit of promoting joint health and comfort. 2012 U.S. Dist. LEXIS 157132, at *1-2. The plaintiff relied upon various studies of Equate's ingredients, glucosamine and chondroitin sulfate, to allege that Equate's representations were deceptive. *Id.* at *21. The court granted the plaintiff's motion to dismiss because the studies the plaintiff relied upon did not "lend 'facial plausibility' to her claims that the Equate representations [were] false or misleading." *Id.* at *27. First, the *Eckler* court explained that "none of these studies actually involved Equate" and thus "the studies simply wouldn't show

[3] Though Plaintiffs argue *Hodges* is inapplicable because it was dismissed under Rule 9(b), *Hodges* actually was dismissed under ***both*** Rule 9(b) and Rule 8(a). 2014 U.S. Dist. LEXIS 5109, at *16-17 ("[T]he [CFA] claim . . . does not meet the Rule 8(a) standard articulated by *Iqbal*, much less Rule 9(b)'s requirement that the circumstances constituting fraud must be stated with particularity."). Rule 9(b) nonetheless applies here. *See* Moving Br. 18, 20-21.

what [plaintiff] claims they do, and the Court would be left with no facts from which to infer that [defendant] is liable for false advertising." *Id.* at *23-25. Second, the court found that there was a "mismatch between the representations at issue and the evidence that allegedly debunks them." *Id.* at *28, 23-24. The court held:

> The studies allegedly show that glucosamine doesn't alleviate the symptoms of osteoarthritis in the hip and knee. That is a very particular showing with respect to a degenerative joint disease, and in the Court's judgment it doesn't address the far more general claim—which ***is*** made by the Equate representations—that glucosamine is good for the body's joints. [*Id.* at *28. (emphasis in original)]

Eckler is on all fours with Plaintiffs' Complaint. Here, the "Absorption study" relied upon to plead falsity did not actually test any of the BodyTech Products, and did not identify an "effective dosage" of Aminogen®. Moreover, the study does not even remotely suggest that the structure/function claims on the BodyTech labels were disproved; instead, the study confirms the accuracy of the labels' statements. *See* McDonald Decl. Ex. C ("Aminogen® . . . may help aid in the absorption and digestion of protein."). In other words, the Absorption study, like the studies the plaintiff tried to rely upon in *Eckler*, did not address "the far more general claim[s]" which were in fact made on the label. 2012 U.S. Dist. LEXIS 157132, at *27.

As such, this case presents precisely the type of "mismatch" between the study and the actual representations on the product that was rejected in *Eckler*. The Complaint otherwise "'cites no studies examining the effectiveness of the actual product in providing the benefits actually represented on the Product label.'" *Id.* at *24-25. Accordingly, just like in *Eckler*, "the Court cannot accept that the studies [Plaintiffs] cite[ ] lend 'facial plausibility' to [their] claims that the [product] representations are false or misleading." *Id.* at *27 (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *see also Toback v. GNC Holdings, Inc.*, 2013 U.S. Dist. LEXIS 131135, at *16 (S.D. Fla. Sept. 13, 2013) ("Plaintiff's allegations regarding the inefficacy of

glucosamine and chondroitin simply fail to address the efficacy of the TriFlex Vitapak's multifarious composition in promoting joint health, and thus fail to raise Plaintiff's claim, that the Vitapak as a whole does not function as advertised, above the speculative level."). The remainder of the cases cited by Plaintiffs are easily distinguished and do not warrant further discussion.[4]

C. The Complaint's Allegations Are Premised Upon Unsupported Inferences and Extrapolations, Not Facts.

There is no question that the "scientific evidence" underpinning Plaintiffs' claims of falsity actually refute those contentions. *First*, and as discussed, the study's findings are entirely ***consistent*** with the Products' label claims. *See* McDonald Decl. Ex. A at 7 ("over-all effect appears to be a significant increase in the WPC absorption rate" and "Aminogen® supplementation may contribute to optimal conditions for protein synthesis and growth"). Therefore, Plaintiffs' reliance upon the studies amounts to their ***concession*** that Aminogen® "may help aid" in the absorption, digestion, and breakdown of protein.

Second, contrary to Plaintiffs' assertions, the clinical studies did ***not*** consider, test, or otherwise set forth a "clinically-proven effective dose[]" of Aminogen®—a term simply not used in the study. Pls.' Br. 8. The study does not state, or even suggest, that lesser dosing rates of Aminogen® would not help aid protein digestion or absorption. Moreover, the "Protein Absorption study" concludes only that, for the dosage amount used ***for purposes of that***

[4] *See Chavez v. Nestle USA, Inc.*, 511 Fed. App'x 606 (9th Cir. 2013) (not addressing lack of substantiation); *Allen v. Hylands, Inc.*, No. CV 12-01150, 2012 U.S. Dist. LEXIS 61606 (C.D. Cal. May 2, 2012) (same); *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 362 (E.D.N.Y. 2010) (not addressing lack of substantiation but rather the defendant's arguments, "the essence of which is that plaintiffs have alleged nothing more than a violation of the Food, Drug, and Cosmetic Act"); *Hoffman v. Liquid Health Inc.*, No. 14-01838, 2014 U.S. Dist. LEXIS 90075, at *2 (D.N.J. July 2, 2014) (not addressing lack of substantiation and involving an allegation of "misrepresenting the product's ingredients" by listing the incorrect amount of an ingredient). Plaintiffs also cherry-pick *FTC v. Medical Billers Network, Inc.*, 543 F. Supp. 2d 283 (S.D.N.Y. 2008), when discussing New York's consumer protection laws. The court in that case, however, discussed solely the ***FTC Act*** when stating the propositions offered by Plaintiffs. *See id.* at *304. Further, the court was ruling on motions for summary judgment, not a motion to dismiss, and did not address lack of substantiation. *See id.* at *289-90.

particular study, the "over-all effect appears to be a significant increase in the WPC absorption rate," and that "Aminogen® supplementation may contribute to optimal conditions for protein synthesis and growth." McDonald Decl. Ex. A at 6-7.

Third, the clinical studies simply do not support Plaintiffs' omission-based claims. Plaintiffs "allege that Defendant ***does not disclose*** the Studies' Aminogen® dosing protocols (3-10% Aminogen®), and ***does not disclose*** that the Products provide substantially smaller doses (only 0.1% Aminogen®) than those used in the Studies." Pls.' Br. 8 (emphasis added). Plaintiffs cite no authority for the proposition that either scientific studies or their results must be disclosed ***because no such authority exists***—study results are not required to be included on a dietary supplement's label. *See* 21 C.F.R. § 101.93(f). Indeed, such an obligation would impose extraordinary, in fact, impossible burdens upon manufacturers of dietary supplements, mandating that for every ingredient in the product, the label must reference clinical studies. Plaintiffs' argument is patently frivolous because it is bereft of any legal or logical support.

Plaintiffs' novel position is that the Products' labels are misleading because they ***imply*** that the quantity (or "dosage") of Aminogen® in the Products is the same as, or similar to, the quantity of Aminogen® that was used in the clinical studies. The studies do not support such an implication, but as set forth more fully *supra*, serve to confirm the accuracy of the BodyTech product line's claims. Further, Plaintiffs' contention that the failure to disclose the studies could lead some to conclude that the BodyTech Products included the same (or even *similar*) Aminogen® doses that were used in the Absorption study, Pls.' Br. 8, is rank speculation which must be ignored under *Twombly* and *Iqbal*.

Overall, Plaintiffs claim that there is not enough Aminogen® in the BodyTech Products for them to be effective because the Absorption study "says so." But the Absorption study said

no such thing, but used a higher dosage of Aminogen® to reach specific findings that Aminogen® supplementation in WPC supports an ***increased rate of protein absorption***; the study did not disprove the BodyTech product line's general claims that it ***may help*** aid, absorb, digest, and break down protein. Regardless, Plaintiffs offer only a claim of lack of substantiation, which is patently impermissible. *See supra* Point I.B; Compl. ¶ 97 ("Defendant has no competent, credible, and reliable scientific evidence . . . to substantiate its claims . . . .").

POINT II

THE LACTASE CLAIMS ARE BASED ON PLAINTIFFS' OWN UNREASONABLE INTERPRETATION OF THE PRODUCT LABEL AND DO NOT STATE PLAUSIBLE CLAIMS.

Plaintiffs all but concede that their allegations regarding lactase lack merit by dedicating only one paragraph in "opposition." *See* Pls.' Br. 11-12. In essence, Plaintiffs continue to advance the illogical theory that the Whey Tech Pro 24 label "is misleading to a consumer who would likely read 'This grouping of enzymes' as referring to Aminogen® and lactase, as lactase is an enzyme." *Id.* at 11. Plaintiffs' tortured reading of the Whey Tech Pro 24 product label is not one that is "plausible" and would not be followed by a reasonable consumer. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-57 (2007). Rather, the interpretation upon which Plaintiffs resort defies logic for the sole purpose of creating a claim for their meritless lawsuit.

Simply put, a reasonable consumer would read "grouping of enzymes" as referring to "Aminogen®, a patented protein enzyme blend," which is the last part of the preceding sentence. *See* Compl. ¶ 24. In other words, "grouping" qualifies "blend" because a "blend" is clearly a "grouping" under any reasonable interpretation of the word. *See, e.g., Blend*, Wikipedia, http://en.wikipedia.org/wiki/Blend (last visited March 25, 2015) ("A 'blend' is a mixture of two or more different things or substances . . . ."). Moreover, the targeted audience that constitutes the reasonable consumer of Whey Tech Pro 24, *i.e.*, those who would be particularly concerned

with the function of lactase, would not reasonably believe that lactase "may held aid in the absorption and digestion of protein" when that is not lactase's function. *See* Compl. ¶ 24.

Lastly, and logically speaking, Defendant would have no incentive to claim that *lactase* aids in the absorption and digestion of protein because *Aminogen*® already performs that very function. Defendant would not gain any advantage by making such a claim. In sum, Plaintiffs have not alleged a plausible false or misleading statement regarding lactase that supports the fraud-based claims in the Complaint.

POINT III[5]

PLAINTIFFS' COMPLAINT SUFFERS FROM ADDITIONAL PLEADING DEFICIENCIES THAT REQUIRE DISMISSAL.

A. Plaintiff Hermida's Forum Shopping Did Not Provide the Requisite Notice For His Breach of Warranty Claim.

Plaintiffs admit that notice is a requirement to plead a breach of express warranty claim in Florida, but creatively argue that the filing of the original complaint in Florida—a blatant attempt to forum shop—serves as the requisite notice. *See* Pls.' Br. 16. Plaintiffs' argument is easily rejected. Florida case law clearly states that "*the Complaint must include an allegation* that notice was given to the seller of the breach." *See, e.g.*, *Randolph v. J.M. Smucker Co.*, No. 13-80581-CIV, 2014 U.S. Dist. LEXIS 33396, at *18 (S.D. Fla. Mar. 14, 2014) (emphasis added). Plaintiffs' ***Complaint*** does not allege that notice was given, and thus Plaintiffs cannot now plead this new allegation in their opposition brief. Further, even if Plaintiffs had alleged in the Complaint that the first lawsuit constituted notice, they offer no support for the proposition that a prior lawsuit constitutes notice. Therefore, the failure to provide requisite notice provides additional grounds for dismissing the breach of express warranty count as to Plaintiff Hermida.

[5] The pleading deficiencies addressed require dismissal under Fed. R. Civ. P. 12(b)(6) and the Court need not proceed further. Defendant, however, responds here to two specific points of law raised by Plaintiffs.

B. Neither Plaintiff Has Standing to Pursue Claims Regarding Primal Pro™.

Plaintiffs' opposition misses the point. Although they state that "Defendant [does not] dispute that Plaintiffs, as individuals, have Article III standing," Pls.' Br. 21, Defendant specifically argued that "Plaintiffs cannot allege a sufficient injury in fact ***with respect to Primal Pro™*** because they did not purchase that product." Moving Br. 24; *see also Dimuro v. Clinique Labs., LLC*, 572 Fed. App'x 27, 29 (2d Cir. 2014) ("Accordingly, Plaintiffs lack class standing to bring claims for the four products that they did not purchase, and these claims were properly dismissed."); *Dapeer v. Neutrogena Corp.*, No. 14-22113, 2015 U.S. Dist. LEXIS 37644, at *11 (S.D. Fla. Mar. 25, 2015) ("Plaintiff lacks Article III standing to bring claims on behalf of the Neutrogena products he did not purchase because he cannot conceivably allege any injuries from products that he never purchased or used."). Here, neither Plaintiff alleged a purchase of Primal Pro™, and therefore all claims relating to that Product must be dismissed.

CONCLUSION

Therefore, Vitamin Shoppe respectfully requests that this Court grant its motion to dismiss all claims in Plaintiffs' Complaint.

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Dated: April 2, 2015

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