

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

DAVID CHAVEZ, individually and on)	
behalf of others similarly situated,)	
)	
Plaintiff,)	
)	
v.)	No. 17 C 1948
)	
CHURCH & DWIGHT CO., INC.)	Judge John J. Tharp, Jr.
)	
Defendant.)	

MEMORANDUM OPINION AND ORDER

With due respect to Mae West, sometimes too much of a good thing isn't wonderful. In this consumer fraud action, Defendant Church & Dwight Co., Inc. ("Church") is accused of understating the amount of folic acid found in its Vitafusion B Complex Adult Vitamin Gummies dietary supplement ("Vitafusion"). Plaintiff David Chavez, an Illinois consumer, alleges that Vitafusion contains more than three times the amount of folic acid per serving declared on the label and that this overabundance is potentially harmful. Chavez seeks, on behalf of himself and several classes of consumers, including nationwide and multistate classes, to hold Church liable for deceptive business practices, fraud, breach of express and implied warranties, and unjust enrichment. Church responded to the amended complaint by filing a motion to dismiss under Rule 12(b)(6), arguing that Chavez's claims are preempted by federal nutrition labeling laws. Alternatively, Church asks the Court to abstain from hearing this case until the Federal Drug Administrative ("FDA") resolves a technical issue at the heart of this dispute. And, as a last resort, Church argues that Chavez cannot represent a class of consumers outside of Illinois due to a lack of standing and personal jurisdiction. Having reviewed the parties' submissions, the Court grants in part and denies in part the motion to dismiss.

BACKGROUND¹

Church is a publically traded Delaware corporation based out of New Jersey that manufactures and distributes household products, including dietary supplements. (Am. Compl. ¶¶ 19, 36, ECF No. 6.) Vitafusion is one of many dietary supplements that Church produces and sells. (*Id.* ¶¶ 1, 39-40.) Church markets Vitafusion as an excellent source of certain B vitamins, including folic acid.² (*Id.* ¶ 40.) According to the nutrition facts listed on the back of a bottle of Vitafusion, one serving (that is, one gummy) provides 400 mcg³ of folic acid,⁴ which is equal to 100% of one's "Daily Value" of the vitamin. (*Id.* ¶¶ 41-42.) Church also advertises on its website that it delivers "high quality dietary supplements in the gummy vitamin industry" and "place[s] the utmost importance on nutritional accuracy and high product quality." (*Id.* ¶ 38.)

Testing by Chavez's counsel shows that Vitafusion gummies contain 1232.2 mcg of folic acid—more than three times the amount listed on the label. (*Id.* ¶ 46.) According to the Office of Dietary Supplements at the National Institute of Health ("NIH"), the Upper Tolerable Intake Limit ("UTIL") for folic acid in a supplement is 1,000 mcg. (*Id.* ¶¶ 32-33.) Consuming more than this amount may cause adverse health effects and, "in some circumstances," could "be dangerous." (*Id.* ¶¶ 29, 33.) The effects include, among others, increasing the risk of heart attack, increasing the risk of certain precancerous tumors becoming malignant, and exacerbating

¹ As it must on a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded facts in the amended complaint and draws all reasonable inferences in the Chavez's favor. *Deb v. Sirva, Inc.*, 832 F.3d 800, 810 (7th Cir. 2016).

² Folic acid is the synthetic form of the B9 vitamin; in its natural state, the vitamin is referred to as folate (or folacin). See *Folate Dietary Supplement Fact Sheet*, National Institute of Health, (updated Mar. 2, 2018), <https://ods.od.nih.gov/factsheets/Folate-HealthProfessional/>; (Am. Compl. ¶¶ 5, 23). The parties appear to use the terms folate and folic acid interchangeably in their briefing. For purposes of this motion, the Court refers to the vitamin only as folic acid.

³ One "mcg" is a microgram, or 1/1000 of a milligram (mg).

⁴ The label specifically lists the vitamin as "Folate, Folic Acid, Folacin." (*Id.* ¶ 41.)

anemia. (*Id.* ¶¶ 30-33.) Chavez purchased and consumed Vitafusion on a number of occasions over the last few years believing that it would provide him with the amount of B vitamins stated on the bottle and benefit his health. (*Id.* ¶¶ 58-60, 62.) He alleges that he would not have done so had he known that the product contained a level of folic acid above the UTIL. (*Id.* ¶¶ 61, 63.)

Chavez brought suit in March 2017 and seeks to represent three classes of Vitafusion consumers: one nationwide, one multistate, and one based in Illinois. (*Id.* ¶¶ 64, 66.) Although the amended complaint comprises six counts, it asserts four claims for relief. The first claim is that Church mislabels the amount of folic acid found in Vitafusion. In Counts I and II, Chavez contends that the mislabeling violates several state consumer laws, including the Illinois Consumer Fraud and Deceptive Business Practices Act (“ICFA”). Count III asserts that the label is fraudulent under Illinois common law, while Counts IV and V contend that the label breaches several express and implied warranties under the Uniform Commercial Code in all fifty states and the District of Columbia. Finally, in Count VI, Chavez seeks to disgorge Church’s Vitafusion revenues under an unjust enrichment theory because the product is mislabeled.

Chavez’s other three claims also relate to Church’s alleged mislabeling of Vitafusion, but are nonetheless distinct. His second claim for relief is that the Vitafusion label fails to disclose that it contains an “unsafe” level of folic acid, while his third claim is that Church misrepresents on its website the quality of its dietary supplements and the level of accuracy of its nutrition labels. Chavez’s legal theory for these claims is that Church’s lack of disclosure and online misrepresentations violate state consumer protection laws (Counts I and II) and constitutes fraud (Count III). Chavez’s final claim, embodied only in Count V, is that because Vitafusion contains an unsafe level of folic acid, the supplement is unfit for consumption.

Church responded to the amended complaint by moving to dismiss. Church argues that Chavez's claims should be dismissed or stayed on several grounds, including preemption, primary jurisdiction, lack of standing, and lack of personal jurisdiction. The Court addresses each argument in turn, beginning with preemption.

DISCUSSION

I. Federal Preemption

Church argues first and foremost that the amended complaint should be dismissed on federal preemption grounds. A dismissal based on federal preemption is a Rule 12(b)(6) dismissal on the merits for failure to state a claim. *See Healy v. Metro. Pier & Exposition Auth.*, 804 F.3d 836, 840-41 (7th Cir. 2015) (citing *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 425 (7th Cir. 2011)). Under Rule 12(b)(6), “a plaintiff must allege ‘enough facts to state a claim to relief that is plausible on its face.’” *Boucher v. Fin. Sys. of Green Bay, Inc.*, 880 F.3d 362, 365-66 (7th Cir. 2018) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 366 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). This Court “must accept as true all factual allegations in the . . . complaint and draw all permissible inferences” in Chavez's favor. *W. Bend Mut. Ins. Co. v. Schumacher*, 844 F.3d 670, 675 (7th Cir. 2016) (internal quotation marks omitted) (quoting *Bible v. United Student Aid Funds, Inc.*, 799 F.3d 633, 639 (7th Cir. 2015)). However, “[w]hile a plaintiff need not plead ‘detailed factual allegations’ to survive a motion to dismiss, he still must provide more than mere ‘labels and conclusions or a formulaic recitation of the elements of a

cause of action’ for [his] complaint to be considered adequate under [Rule] 8.” *Bell v. City of Chicago*, 835 F.3d 736, 738 (7th Cir. 2016) (quoting *Iqbal*, 556 U.S. at 678).⁵

There are three types of preemption: express preemption, conflict preemption, and field preemption. *Bible*, 799 F.3d at 651-52 (citing *Aux Sable Liquid Prods. v. Murphy*, 526 F.3d 1028, 1033 (7th Cir. 2008)). Church relies only on express preemption, which “occurs when a federal statute explicitly states that it overrides state law or local law.” *Aux Sable*, 526 F.3d at 1033 (citation omitted). There is a strong presumption against preemption, *Patriotic Veterans, Inc. v. Indiana*, 736 F.3d 1041, 1046 (7th Cir. 2013); *see also Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (“[W]e start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act”) (internal quotation marks and citation omitted), and Church bears the burden of overcoming it, *Russian Media Grp., LLC v. Cable Am., Inc.*, 598 F.3d 302, 309 (7th Cir. 2010) (citation omitted).

A. Preemption under the NLEA

The issue here is whether the amended complaint is preempted by the labeling requirements of the Food, Drug, and Cosmetic Act (“FDCA”), as amended by the Nutrition Labeling and Education Act (“NLEA”). The NLEA includes an express preemption provision that prohibits states from establishing any requirements that are “not identical to” certain federal requirements for the labeling of food and dietary supplements. 21 U.S.C. § 343-1(a); *see also Krommenhock v. Post Foods, LLC*, 255 F. Supp. 3d 938, 951 (N.D. Cal. 2017) (discussing

⁵ Although Counts I, II, and III assert causes of action for fraud and deceptive business practices, Church does not challenge those counts on the basis Rule 9(b). As such, the Court does not consider in this motion whether Chavez has stated “with particularity the circumstances” underlying those causes of action. Fed. R. Civ. P. 9(b).

general framework of preemption under the NLEA).⁶ In particular, the provision expressly preempts any state requirements for nutrition labeling that are not identical to the requirements of section 343(q) of the FDCA. 21 U.S.C. § 343-1(a)(4). It also preempts states from imposing requirements on nutrient-content or health-related claims made on a label that are not identical to the requirements set forth in section 343(r) of the Act. *Id.* § 343-1(a)(5).

The phrase “not identical to” means that a state requirement imposes an obligation that is “not imposed by or contained in” or “[d]iffer[s] from those specifically imposed by or contained in” the FDCA or FDA regulations. 21 C.F.R. § 100.1(c)(4); *see also Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (“Federal regulations have no less pre-emptive effect than federal statutes.”). Moreover, the Supreme Court has explained that the preemptive effect of the “requirements” language in § 343-1 “reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties.” *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005). Chavez’s claims then, whether rooted in positive or common state law, are preempted if they directly or indirectly impose a labeling requirement on Church that is not already “imposed by § 343(q), § 343(r), or the implementing regulations for those provisions.” *Gubala v. CVS Pharmacy, Inc.*, No. 14 C 9039, 2016 WL 1019794, at *4 (N.D. Ill. Mar. 15, 2016). Conversely, Chavez’s claims survive dismissal if they merely seek to enforce those requirements; litigants may “enforce a violation of the Act as a violation of state law.” *Turek*, 662 F.3d at 426 (“This is important because the [FDCA] does not create a private cause of action.”); *see also Beverages: Bottled Water*, 60 Fed. Reg. 57076, 57120 (Nov. 13, 1995)

⁶ Dietary supplements are deemed to be “food” under the FDCA, 21 U.S.C. § 321(ff), so the NLEA’s preemption provision extends to labeling requirements for supplements as well. Moreover, the parties do not dispute that Vitafusion meets the definition of dietary supplement.

(adding that “if the State requirement does the same thing that the Federal law does, . . . then it is effectively the same requirement as the Federal requirement” and not subject to preemption).

B. FDA Regulation of Folic Acid Declarations

The first step in unpacking Church’s preemption defense is to determine what the FDCA has to say about the labeling of folic acid in dietary supplements. Under certain circumstances that are not in dispute here, the Act requires manufacturers to list folic acid as an ingredient on a supplement’s nutrition label. *See* 21 U.S.C. § 343(q)(5)(F)(i); 21 C.F.R. § 101.9(c)(8)(ii); 21 C.F.R. § 101.36(b)(2). When folic acid is declared on a label, the FDCA dictates that the label include “the quantity of [folic acid] per serving.” 21 U.S.C. § 343(q)(5)(F)(ii); *see also* 21 C.F.R. § 101.9(c)(8)(iii) (“The quantitative amounts of vitamins and minerals, excluding sodium, shall be the amount of the vitamin or mineral included in one serving of the product.”). Moreover, the Act requires that the label accurately report the amount of folic acid found in the supplement; otherwise, the label is misbranded. *See* 21 U.S.C § 343(a) (“A food shall be deemed misbranded [if] its labeling is false or misleading in any particular . . .”).

FDA regulations specify when a labeled amount of folic acid is deemed to be accurate. Folic acid is a Class I nutrient (at least in the context of this litigation),⁷ so the Court must look to 21 C.F.R. § 101.9(g)(4)(i) for guidance. Under that provision, a dietary supplement that includes a vitamin declaration “shall be deemed to be misbranded under [21 U.S.C. § 343(a)] unless” the content of the vitamin in the supplement is “at least equal to” the amount of the

⁷ Class I nutrients are those “[a]dded . . . in fortified or fabricated foods[.]” 21 C.F.R. § 101.9(g)(3)(i). They stand in contrast to Class II nutrients, which are “[n]aturally occurring (indigenous) nutrients.” *Id.* § 101.9(g)(3)(ii). The parties seem to agree that the folic acid added to Vitafusion is a Class I nutrient, (*see* Def. Mot. to Dismiss 6, ECF No. 23; Am. Comp. ¶ 12), and the Court see no reasons to alter that characterization.

vitamin declared on the label. 21 C.F.R. § 101.9(g)(4)(i).⁸ That is, a nutrition label is deemed inaccurate (or misbranded in FDCA parlance) when it *overstates* the amount of folic acid in a supplement. A supplement that contains more folic acid than the label suggests would not run afoul of this particular requirement.

Section 101.9(g)(4)(i), moreover, is not the only regulation that bears on the accuracy of a folic acid declaration. When folic acid is *understated* on a label, section 101.9(g)(6) enters the fray. That provision provides: “Reasonable excesses of vitamins . . . over labeled amounts are acceptable within current good manufacturing practice.” 21 C.F.R. § 101.9(g)(6). The FDA does not define reasonable excess, but it does provide guidance on current good manufacturing practice (“cGMP”). Relevant to this dispute is a cGMP regulation that requires manufacturers to keep track of “any intentional overage amount of a dietary ingredient.” 21 C.F.R. § 111.210(e). An overage refers to the quantity of an ingredient added to ensure that the ingredient meets the amount specified on the label throughout the product’s shelf life. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34752, 34884 (June 25, 2007). When the FDA initially proposed this regulation, it referred to the additional amount as an “intentional excess.” Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Dietary Ingredients or Dietary Supplements, 68 Fed. Reg. 12158, 12203 (Mar. 13, 2003). But in enacting the final regulation, the FDA commented that the additional amount was more commonly known as an “overage” in the supplement industry, and so adopted that term. 72 Fed. Reg. at 34884. In either case, the FDA cautioned that the provision “is not intended to allow a manufacturer to add . . . unspecified amounts [of an ingredient] that would be in excess of the amount actually needed to meet the

⁸ Although the provision applies explicitly to “food” labels, 21 C.F.R. § 101.36(f)(1) extends the provision’s reach to dietary supplement label as well.

label declaration.” 68 Fed. Reg. at 12158; *accord* 72 Fed. Reg. at 34884 (“As discussed in the preamble to the 2003 CGMP Proposal . . . , the amount of overage should be limited to the amount needed to meet the amounts listed in accordance with final § 111.210(d).”).

C. Express Preemption of Plaintiff’s Claims

With this framework in mind, the Court turns to the preemption dispute, which focuses almost exclusively on Chavez’s mislabeling claim. Church believes that the mislabeling claim is preempted for two reasons, the first of which is that it fails to address the reasonable excess exception. (Def. Mot. 5-6.) According to Church, for the mislabeling claim to survive dismissal, Chavez “must plausibly allege the excess [in Vitafusion] is not consistent with current good manufacturing practice for ensuring that the folate level does not fall below the labeled amount during the product’s shelf life.” (Def. Reply in Supp. of Mot. to Dismiss 10, ECF No. 28.) Because Chavez fails to even mention the exception in the amended complaint, Church continues, the claim must be dismissed. Chavez rejoins that he need not plead around the exception but, even if he does, he has alleged more than enough facts to infer that the excess folic acid in Vitafusion is unreasonable and outside of good manufacturing practices. (Pl. Resp. to Def. Mot. to Dismiss 6-7, ECF No. 27.)

At the outset, the Court agrees with Church that the mislabeling claim must be consistent with the reasonable excess exception to survive dismissal. Chavez contends that he need only allege that the Vitafusion label “list an inaccurate quantity” of folic acid for his mislabeling claim to avoid preemption. (*Id.* at 6.) What Chavez means by inaccurate here is that *any* discrepancy between the actual and labeled amounts of folic acid in a supplement constitutes a violation of the FCDA. But that is not so. To be sure, the Act flatly bars Church from overstating the amount of folic acid in Vitafusion. *See CreAgri, Inc. v. USANA Health Sci., Inc.*, 474 F.3d 626, 631 (9th Cir. 2007) (“Because the actual amount of hydroxytyrosol (at most 3mg) was less

than the values . . . declared on Olivenol’s label (25 mg and 5mg), [the] product was . . . in violation of 21 C.F.R. § 101.9(g)(4)(i).”). But, as explained above, the FDCA permits manufacturers to under declare folic acid by a reasonable amount. Chavez seeks to hold Church liable for understating the quantity of folic acid, so whether the mislabeling claim is preempted turns on whether the folic acid discrepancy in Vitafusion was within the “reasonable excess” provision of the regulation.

Where the Court parts ways with Church is its contention that the amended complaint does not plausibly allege a violation of the reasonable excess provision. Chavez alleges that the concentration of folic acid in Vitafusion is over 300% greater than the amount listed on the label. (Am. Compl. ¶¶ 41, 46.) He further asserts that the actual amount of folic acid in Vitafusion is potentially dangerous and may cause severe adverse health effects. (*Id.* ¶¶ 31-33, 45.) This is not, as Church maintains, “rank speculation.” (Def. Reply 6.) Given that the Court is required to accept all well-pleaded facts as true and construe all reasonable inferences in the Chavez’s favor, these allegations are enough to suggest that Church added more folic acid to Vitafusion than was necessary to ensure that the level of folic acid meets the labeled amount over the course of the supplement’s shelf life. It is surely plausible to infer that adding dangerous amounts of folic acid to Vitafusion is not consistent with cGMP. Thus, even under Church’s reading of the reasonable excess provision (more on that below), the mislabeling claim is plausibly consistent with federal labeling law. To be sure, it remains to be seen whether the predicate for Chavez’s argument bears up under scrutiny. But his claim that including harmful levels of folic acid falls outside the bounds of reasonableness or cGMP is by no means implausible.

Before moving on, there are two issues concerning Church’s reading of the reasonable excess provision that merit discussion. First, Church assumes that Chavez bears the burden under

§ 101.9(g)(6); that is, he bears the burden to plead and prove that the amount of folic acid was unreasonable in light of cGMP. But it is not clear whether that is the case. The issue boils down to how the “at least equal to” and “reasonable excess” provisions should be read together. It is possible to interpret the two regulations, as Church seems to, to mean that a label that understates the content of a nutrient is FDA compliant unless the difference between the labeled and actual amount is an unreasonable excess. When viewed in this light, Chavez would bear the burden of showing that any excess was unreasonable. But another possible way to read these regulations—especially in light of the FDCA’s general prohibition against false and misleading statements—is that any discrepancy between the actual and labeled amounts constitutes a *prima facie* misbranding violation. Under this view, the reasonable excess provision serves as a safe harbor and Church would bear the burden of seeking its protection. *See, e.g., EEOC v. Chicago Club*, 86 F.3d 1423, 1429 (7th Cir. 1996) (“It is a commonly accepted canon that [o]ne who claims the benefit of an exception for the prohibition of a statute has the burden of proving that his claim comes within the exception.”) (internal quotation marks and citation omitted). The Court need not resolve this question now, as it concludes that Chavez plausibly states a claim for mislabeling even if he bears the burden of proof. But the parties may need to address this issue going forward if the litigation proceeds past the discovery stage.

Second, Church suggests that the application of the reasonable excess provision turns solely on whether an excess is necessary to ensure a nutrient declaration is accurate during the shelf life of product.⁹ Put somewhat differently, Church argues that “excesses” and “overages” are one in the same. But it is not evident from the FDA’s commentary whether overages are

⁹ In its opening brief, Church states that the shelf-life issue is only “one question [the] FDA would consider” in addressing the reasonable excess provision. (Def. Mot. 6.) But Church goes further in its reply, arguing that the Chavez “must plausibly allege” that the additional folic acid in Vitafusion is not an overage. (Def. Reply 10.)

synonymous with, or merely a subset of, excesses. In theory, an excess could result from some reason other than addressing shelf-life concerns, such as when a variance occurs a result of the manufacturing process itself. The Court need not unravel this issue either; it suffices at this point to note that Church has not shown that the degradation of a nutrient over the product's shelf life is the *only* relevant consideration under § 101.9(g)(6).

Church advances one other challenge to Chavez's mislabeling claim, but it too is wanting at this stage. Church contends that the claim is preempted because the FDA has not set an upper limit on the amount of folic acid that may be added to supplements. (Def. Mot. 6-7.) While the NIH may recommend a UTIL of 1,000 mcg, Church argues, a manufacturer does not violate the FDCA by exceeding that threshold. But even assuming Church is correct in asserting that the FDA does not recognize a UTIL for folic acid—an issue Chavez disputes—it does not follow that the mislabeling claim is preempted. Chavez's theory is that the Vitafusion label misleads consumers because it grossly understates the amount of folic acid. That the actual amount of folic acid in Vitafusion exceeds the UTIL set by the NIH is relevant because it is evidence—though by no means conclusive—that the excess folic acid in Vitafusion is unreasonable and thus inconsistent with § 101.9(g)(6). To be sure, whether the FDA recognizes a 1,000 mcg upper limit bears on the reasonable excess analysis as well. But contrary to Church's contention, it does not resolve the issue conclusively. At bottom then, Chavez plausibly alleges that Vitafusion is misbranded within the confines of the FDCA and thus the Court cannot conclude at this stage that his mislabeling claim is preempted.

Nor can the Court conclude that Chavez's other three claims are preempted. Church argues that because Chavez's claims are all "premised on the same allegations," the rest of the claims are preempted for the same reason as the mislabeling claim. (Def. Mot. 8.) Given that the

Court finds the mislabeling claim is not subject to preemption at the pleading stage, this argument lacks any force. But even setting that argument aside, two of the remaining three claims are not even implicated by the NLEA's preemption statute. As Church points out, the statute applies only to claims that impose requirements on the labeling or packaging of food—or in this case, dietary supplements. (*Id.* at 5 (citing *Reyes v. McDonald's Corp.*, No. 06 C 1604, 2006 WL 3253579, at *5 (N.D. Ill. Nov. 8, 2006).) Unlike his mislabeling claim, though, Chavez's misrepresentation claim is based on statements made on Church's *website*, not on any product label or packaging. *See Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 780, 807 (N.D. Cal. 2015) (rejecting application of NLEA preemption to statements made on defendant's website because defendant "pointed to no provision of the FDCA or FDA regulations that preempts claims based on such alleged misrepresentations, which are not alleged to be included on product labels or packaging"). And as for Chavez's fitness claim, the crux of that claim is that Vitafusion is not fit for consumption. (Am. Compl. ¶¶ 13, 40, 120.) Thus, it does not implicate any of the FDCA's labeling or packaging requirements either.

The Court is left then only with Chavez's claim that Vitafusion fails to warn consumers that it contains an unsafe level of folic acid. This claim falls squarely within the reach of § 343(a) as it impliedly requires Church to add an additional warning to the Vitafusion label. The problem here is that Church does not provide the Court with a basis to conclude that such a warning goes beyond the requirements of the FDCA. Church vigorously contends that the amount of folic acid in Vitafusion is in fact safe, but does not address the relevant question for preemption: does the FDCA impose any requirements on manufacturers to disclose potential adverse effects of consuming certain levels of nutrients? To be sure, Church's position likely is that no such requirement exists, especially given that it argues elsewhere that the FDA does not limit the

amount of folic acid that may be used in supplements. But Church does not stake out that position in its brief. Nor does its discussion about the limits of folic acid usage (or lack thereof) make clear whether the FDA imposes any sort of obligation to warn consumers about overconsumption of nutrients and if so, under what circumstances. Church bears the initial burden to properly put the defense of preemption before the Court, *Russian Media*, 598 F.3d at 309, but has failed to meet that burden with regard to the nondisclosure claim. The Court cannot conclude, on the basis of Church's argument, that the non-disclosure claim is preempted. Church's motion to dismiss based on federal preemption is denied.

II. Primary Jurisdiction

As a back stop to preemption, Church asks the Court to stay or dismiss this case under the doctrine of primary jurisdiction to allow the FDA to determine whether the amount of folic acid in Vitafusion is in fact protected by the reasonable excess provision.¹⁰ Primary jurisdiction encompasses two concepts; one of exclusive agency jurisdiction and one of abstention. *Arsberry v. Illinois*, 244 F.3d 558, 563 (7th Cir. 2001). Church invokes the latter concept here, under which, a district court may refer an issue over which it has jurisdiction to an agency with specialized expertise or knowledge for resolution. *Reiter*, 507 U.S. at 268 (stating that the doctrine "requires the court to enable a 'referral' to the agency, . . . so as to give the parties reasonable opportunity to seek an administrative ruling"); *In re StarNet, Inc.*, 355 F.3d 634, 639 (7th Cir. 2004) (explaining that the doctrine, "in its weaker sense" allows "a court to refer an issue to an agency that knows more about the issue"). There is no "fixed formula" for deciding

¹⁰ Although Church seeks either a stay or dismissal, a dismissal would not be warranted even if the doctrine applies. See *Reiter v. Cooper*, 507 U.S. 258, 268 (1993) (stating that the doctrine results in "*staying* further proceedings") (emphasis added) (citation omitted); see also *Ryan v. Chemlawn Corp.*, 935 F.2d 129, 132 n.2 (7th Cir. 1991) (discussing in dicta strong preference for issuing stay, rather than dismissal without prejudice, on primary jurisdiction grounds). As such, the Court will consider only whether a stay is warranted.

whether to abstain under primary jurisdiction; rather, a case-by-case determination must be made in light of the purpose of the applicable statute and the relevance of the administrative expertise. *Ryan*, 935 F.2d at 131 (citation omitted). Considerations that animate this decision include whether (1) invoking the doctrine promotes consistency and uniformity, (2) the agency is uniquely qualified to resolve a complex issue that is outside the conventional experience of the courts, and (3) the application of the doctrine serves judicial economy because the dispute may be decided within the agency. *Id.* (citations omitted).

Church believes that abstention is warranted for two reasons. First, the principal issue in this case requires scientific and industry expertise that the FDA has and this Court lacks. (Def. Mot. 10-12.) In particular, Church contends that the dispute turns on the reasonable excess provision and construing that provision will require knowledge of folate levels, folate safety, and cGMP in the vitamin field. (*Id.* at 11.) Second, interpreting the regulation is a matter of first impression and, as such, the Court should default to the FDA to ensure consistency and uniformity in the field of nutrition labeling. (*Id.*) Chavez counters that the Court should press forward with this case because it is capable of interpreting regulations and because Church has failed to show that the FDA is contemplating issuing specific guidance on the reasonable excess provision. (Pl. Resp. 10-13.) Chavez has the better of this argument.

The principal difficulty with applying the primary jurisdiction doctrine here is that Church has not identified any relevant proceedings to which this Court should defer in resolving the reasonable excess issue. Absent some plausible proposal for obtaining a determination from the FDA, a stay would do nothing more than hold Chavez's claim in limbo. If Church were serious about deferring this issue to the FDA, it presumably would have explained what administrative proceedings could be initiated that would definitively interpret the provision and

adjudicate Vitafusion's compliance. *See Natural Res. Def. Council v. Metro. Water Reclamation Dist. of Greater Chi.*, 175 F. Supp. 3d 1041, 1048 (N.D. Ill. 2016) (rejecting primary jurisdiction argument on same basis); *Biffar v. Pinnacle Foods Grp., LLC*, No. 16-0873-DRH, 2016 WL 7264973, at *2 (S.D. Ill. Dec. 15, 2016) (declining to stay action on primary jurisdiction grounds in suit alleging muffin mix label was deceptive because benefits of stay were speculative and stay would unduly prejudice plaintiff).

Church also overstates the need to rely on the FDA's expertise. Federal district courts are well equipped to interpret agency regulations, including those involving current good manufacturing practices. *See Gubala*, 2016 WL 1019794, at *16 (stating that district courts are "well qualified to interpret [agency] regulation" in rejecting primary jurisdiction argument); *Bausch v. Stryker Corp.*, 630 F.3d 546, 556 (7th Cir. 2010) (stating that interpretation cGMP regulations "present[s] questions of law for the court to decide" that is "subject to the usual processes for reconciling conflicting views"). Moreover, this case primarily concerns allegations of false and misleading representations, the sort of allegations that district courts routinely address. *See, e.g., Biffar*, 2016 WL 7264973, at *2 (adding that district courts are "well-suited to entertain . . . consumer fraud case[s]"). To be sure, the Court may need to evaluate scientific evidence at some point in this case. But it is not apparent at this stage that the FDA's expertise will be required in order to do so, especially when Church has not articulated exactly how the agency would adjudicate the reasonable excess issue at hand.

Finally, while Church's concerns about consistency and uniformity carry some weight, they do not tip the scale in favor of a stay. The FDA somewhat recently has indicated that it is contemplating additional guidance relevant to the reasonable excess provision. In a final rule issued in May 2016, the FDA reported that it had received comments that "expressed concern

that firms may include large excesses (greater than 120 percent of the declared amount) to remain in compliance with requirements for Class I nutrients and other dietary ingredients over the shelf life of the product.” Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33742, 33964 (May 27, 2016). In response to those public comments, the FDA stated that “[p]roduct loss over the shelf-life of a product is a complex issue” as to which it “needs additional time to review available information and to make a determination whether to propose changes with respect to the requirements for Class I nutrients.” *Id.* at 33965. What the Court gleans from these statements is that the FDA may issue overage requirements or restrictions for folic acid and other Class I nutrients. The problem with issuing a stay on this basis is that there is no indication of when, if ever, the FDA will act. Even if the FDA does act in the near future, there also is no guarantee that it would squarely address the issues raised in this litigation. *See Krommenhock*, 255 F. Supp. 3d at 969 (declining to issue stay due to the lack of “evidence that final action (or any further clarification as to the scope of the FDA’s review of the regulation at issue) is imminent”); *Burton v. Hodgson Mill, Inc.*, No. 16-CV-1081-MJR-RJD, 2017 WL 1282882, at *8 (S.D. Ill. Apr. 6 2017) (rejecting argument that court should grant stay to allow FDA time to formulate definition of term “all natural” because agency had not issued timeframe for decision and stay would unnecessarily protract litigation). Therefore, given the uncertainty and the likely prejudice Chavez would face if granted, the Court declines to issue a stay based on the primary jurisdiction of the FDA.

III. Nationwide and Multistate Class Claims

Church’s next argument is that Chavez is barred from asserting any claims on behalf of putative class members outside of Illinois. According to Church, there are two reasons why that

is the case: lack of standing and lack of personal jurisdiction.¹¹ Because the Court agrees with Church that the claims of out-of-state residents do not provide this Court with a basis to exercise personal jurisdiction over Church, it need not consider the standing challenge.

Although Church's motion expressly invokes only Rule 12(b)(6), a dismissal for lack of personal jurisdiction is governed by Rule 12(b)(2). A complaint is not required to include facts alleging personal jurisdiction, but when a defendant moves to dismiss under Rule 12(b)(2), the plaintiff bears the burden of demonstrating personal jurisdiction over the defendant. *N. Grain Mktg., LLC v. Greving*, 743 F.3d 487, 491 (7th Cir. 2014). Where, as here, the parties rely solely on written materials, the plaintiff need only establish a *prima facie* case for personal jurisdiction. *Id.* In determining whether that burden has been met, the Court resolves any factual disputes in the plaintiff's favor, *id.*; though, the facts material to jurisdiction in this case are not in dispute.

Where no federal statute authorizes nationwide service of process, federal courts look to state law to determine the limits of their personal jurisdiction over a party. Fed. R. Civ. P. 4(k)(1)(A). The Illinois long-arm statute permits courts to exercise personal jurisdiction up to the limits of the Due Process Clause of the Fourteenth Amendment. 735 ILCS 5/2-209(c); *Kipp v. Ski Enter. Corp. of Wis.*, 783 F.3d 695, 697 (7th Cir. 2015). "Thus, the state statutory and federal constitutional requirements merge." *Brook v. McCormley*, 873 F.3d 549, 552 (7th Cir. 2017). The Due Process Clause limits the power of courts to render judgments over nonresident defendants; personal jurisdiction arises only when the defendant has "certain minimum contacts

¹¹ Although Church raised its personal jurisdiction challenge for the first time in its reply brief, the Court declines to deem that argument as waived for two reasons. First, the argument is premised squarely on *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773 (2017), a decision that was not handed down until after Church filed its motion to dismiss. (Def. Reply 14.) Second, Chavez had an adequate opportunity to respond. He preemptively addressed *Bristol-Myers* in his response brief, (Pl. Resp. 14), and also filed a sur-reply, (Pl. Sur-Reply in Opp'n to Def. Mot. to Dismiss, ECF No. 32). While Chavez did not use his sur-reply to address personal jurisdiction, he could have had he thought it was necessary.

with [the forum state] such that the maintenance of the suit does not offend ‘traditional notions of fair play and substantial justice.’” *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (citations omitted). Although physical presence in the forum is not required, the defendant must have sufficient minimum contacts such that it “should reasonably anticipate being haled into court there.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985) (quoting *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980)).

In *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773 (2017), the Supreme Court considered several suits in California state court by a number of California residents and nonresidents against a pharmaceutical manufacturer who was not subject to general jurisdiction in California. *Id.* at 1778. The plaintiffs alleged that they were harmed by the manufacturer’s drug Plavix; however, none of the nonresidents had purchased, consumed, or were prescribed Plavix in California. *Id.* The California Supreme Court held that there was specific jurisdiction over the nonresidents’ claims because they were “similar in several ways to the claims of the California residents (as to which specific jurisdiction was uncontested).” *Id.* at 1778-79. The United States Supreme Court disagreed, holding that there was an insufficient link between California and the nonresidents’ claims to support specific jurisdiction given that none of the conduct giving rise to those claims occurred in California. *Id.* at 1781. The Court explained, “[t]he mere fact that *other* plaintiffs were prescribed, obtained, and ingested Plavix in California—and allegedly sustained the same injuries as did the nonresidents—does not allow the State to assert specific jurisdiction over the nonresidents’ claims.” *Id.* In so holding, the Court emphasized two principles of personal jurisdiction. It first reiterated that the “primary focus of [the] personal jurisdiction inquiry is the defendant’s relationship with the forum state.” *Id.* at 1779. It then reaffirmed that the jurisdictional inquiry “encompasses the more abstract matter of

submitting to the coercive power of a State that may have little legitimate interest in the claims in question.” In some cases, the Court continued, the Due Process Clause of the Fourteenth Amendment, “acting as an instrument of interstate federalism” serves to “divest the State of its power to render a valid judgment.” *Id.* (quoting *World-Wide Volkswagen*, 444 U.S. at 294).

Relying on *Bristol-Myers*, Church contends that, because it is not subject to general jurisdiction in Illinois,¹² it may be sued in Illinois only by consumers whose claims arise out of Church’s contacts with Illinois, *i.e.*, those who purchased or consumed Vitafusion in Illinois. (Def. Reply 14.) The import of this argument is that Chavez may not assert claims on behalf of either a nationwide or multistate class. Chavez does not argue that Church’s understanding of *Bristol-Myers* is flawed; rather, he contends that the holding is inapplicable here because that case involved a mass action while this suit is a class action. (Pl. Resp. 14 n.5.) In support, Chavez cites to Justice Sotomayor’s dissent in *Bristol-Myers*, in which she noted that the majority left open the question of whether its holding “would also apply to a class action in which a plaintiff injured in the forum State seeks to represent a nationwide class of plaintiffs, not all of whom were injured there.” 137 S. Ct. at 1789 n.4.

Whether *Bristol-Myers* extends to class actions is a question that has divided courts across the country. A number of district courts have concluded that the distinction between mass and class actions limits the reach of the Supreme Court’s holding. *E.g.*, *In re Chinese-Manufactured DryWall Prods.*, Civ. Act. MDL No. 09-2047, 2017 WL 5971622, at *13-16 (E.D. La. Nov. 30, 2017) (finding *Bristol-Myers* to be inapplicable to class actions, in part, because

¹² The parties agree that Church is incorporated in Delaware and has its principal place of business in New Jersey. (Am. Compl. ¶ 20; Def. Reply 14.) Moreover, Chavez does not allege any facts that give rise to the inference that Church’s operations are so substantial in Illinois as to render it essentially at home in the state. *See BNSF Ry. Co. v. Tyrrell*, 137 S. Ct. 1549, 1558 (2017) (citations omitted).

class actions have due process safeguards under Rule 23 that mass actions lack); *Fitzhenry-Russell v. Dr. Pepper Snapple Grp., Inc.*, No. 17-cv-00564 NC, 2017 WL 4224723, at *5 (N.D. Cal. Sept. 22, 2017) (holding that “*Bristol-Myers* is meaningfully distinguishable based on that case concerning a mass tort action, in which each plaintiff was a named plaintiff”). Other district courts, including several within this district, have concluded that the distinction is irrelevant and have applied *Bristol-Myers* to class actions. *E.g.*, *Practice Mgmt. Support Servs., Inc. v. Cirque du Soleil, Inc.*, No. 14 C 2032, 2018 WL 1255021, at *16 (N.D. Ill. Mar. 12, 2018) (holding that defendants cannot “distinguish the Supreme Court’s basic holding in *Bristol-Myers* simply because this is a class action”); *DeBernardis v. NBTY, Inc.*, No. 17 C 6125, 2018 WL 461228, at *2 (N.D. Ill. Jan. 18, 2018) (“The Court believes that it is more likely than not . . . that the courts will apply *Bristol-Myers Squibb* to outlaw nationwide class actions . . . where there is no general jurisdiction over the Defendants.”); *McDonnell v. Nature’s Way Prods., LLC*, No. 16 C 5011, 2017 WL 4864910, at *4 (N.D. Ill. Oct. 26, 2017) (stating that “the analysis used in *Bristol-Myers Squibb Co.* is instructive in considering whether the Court has personal jurisdiction over the claims” of non-Illinois class members).

This Court finds the latter line of cases to be persuasive. Nothing in *Bristol-Myers* suggests that its basic holding is inapplicable to class actions; “rather, the Court announced a general principle—that due process requires a ‘connection between the forum and the specific claims at issue.’” *Greene v. Mizuho Bank, Ltd.*, No. 14 C 1437, 2017 WL 7410565, at *4 (N.D. Ill. Dec. 11, 2017) (citing *Bristol-Myers*, 137 S. Ct. at 1781). To the contrary, the Court’s concerns about federalism suggest that it seeks to bar nationwide class actions in forums where the defendant is not subject to general jurisdiction. *See DeBernardis*, 2018 WL 461228, at *2. And, as Judge Durkin recently pointed out, “[u]nder the Rules Enabling Act, a defendant’s due

process interest should be the same in the class context” as it is in individual or mass actions. *Practice Mgmt.*, 2018 WL 1255021, at *16 (“Rule 23’s [class action] requirements must be interpreted in keeping with Article III constraints, and with the Rules Enabling Act, which instructs that the [federal court] rules of procedure shall not abridge, enlarge, or modify any substantive right.”) (alterations in original) (internal quotation marks omitted) (quoting *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 592 (1997)).

Further, the Court is unpersuaded by the reliance of some district courts on the fact that the citizenship of unnamed class members is disregarded for purposes of determining diversity—that is, subject matter—jurisdiction. The question here is not whether this Court has subject matter jurisdiction, but whether, consistent with due process, this Court may exercise specific personal jurisdiction over a defendant with regard to claims that have no connection with this state beyond their similarity to claims asserted by other plaintiffs who are residents of this state. The focus of the due process inquiry is on whether the defendant’s contacts with the state of Illinois give rise to the claims of nonresident plaintiffs. Whether the citizenship of unnamed class members should be disregarded for purposes of determining whether diversity jurisdiction exists simply has no relevance to the answer to that question.

The Court therefore concludes that *Bristol-Myers* extends to class actions, and that Chavez is therefore foreclosed from representing either a nationwide and multistate class comprising non-Illinois residents in this suit. Accordingly, the Court dismisses those claims under Rule 12(b)(2) without prejudice to being reasserted in a court that can exercise personal jurisdiction over the defendant. *See DeBernardis*, 2018 WL 462338, at *2 (granting motion to dismiss the claims of “out-of-state plaintiff classes”); *McDonnell*, 2017 WL 4864910, at *4-5 (dismissing claims of non-Illinois class members).

IV. Remaining Arguments

Before closing, the Court must address two arguments that Church raises in footnotes in its opening brief—neither of which prompted a response from Chavez.¹³ First, Church contends that Chavez’s online misrepresentation claim fails because he does not allege that he read any of the statements on Church’s website before purchasing Vitafusion. (Def. Mot. 7 n.4.) The Court agrees. To succeed on his misrepresentation claim, which is predicated on the ICFA and common law fraud, Chavez must plead and prove that the online statements proximately caused the harm he claims (ICFA) or that he justifiably relied on the statements to his detriment (common law fraud). *Newman v. Metro. Life. Ins. Co.*, 855 F.3d 992, 1000, 1003 (7th Cir. 2018) (outlining elements of both causes of action). By failing to allege that he read the statements on Church’s website, there is no basis to conclude that Chavez relied on them in purchasing Vitafusion or that they induced him to purchase the supplement. Thus, the Court dismisses Chavez’s online misrepresentation claim pursuant to Rule 12(b)(6). The dismissal, however, is without prejudice; Chavez has leave to re-plead his claim to address this issue, if he is able.

Second, Church challenges the viability of Count VI. It contends that unjust enrichment is not an independent cause of action and must be dismissed because it is predicated on Chavez’s claims under the ICFA. (Def. Mot. 8 n.5.) Church is wrong on both accounts. For starters, the Illinois Supreme Court on several occasions has described unjust enrichment as an independent cause of action. *See, e.g., Raintree Homes, Inc. v. Village of Long Grove*, 209 Ill. 2d 248, 807 N.E.2d 439, 445 (2004) (observing that “plaintiffs have no substantive claim grounded in tort, contract, or statute; therefore the only substantive basis for the claim is restitution to prevent

¹³ The Court cautions the parties going forward about raising arguments in footnotes. The Seventh Circuit has reiterated time and again that skeletal and undeveloped arguments raised in footnotes are subject to waiver. *See, e.g., Harmon v. Gordon*, 712 F.3d 1044, 1053 (7th Cir. 2013); *Hernandez v. Cook Cty. Sherriff’s Office*, 634 F.3d 906, 913 (7th Cir. 2011).

unjust enrichment”). Church’s argument to the contrary is based not on more recent Illinois Supreme Court authority than *Raintree*, but on the Seventh Circuit’s decision in *Pirelli Armstrong Tire Corp. Retiree Medical Benefits Trust v. Walgreen Co.*, a case in which the Court of Appeals held that unjust enrichment is not a standalone claim under Illinois law. 631 F.3d 436, 447 (7th Cir. 2011). But Church fails to realize that the Seventh Circuit altered course several months later in *Cleary v. Phillip Morris Inc.*, 656 F.3d 511 (7th Cir. 2011). After examining the issue more closely, the Court of Appeals acknowledged that it was an open question as to whether unjust enrichment may be redressed through a separate cause of action. *Id.* at 518. In all events, the distinction matters little here. Because Chavez’s mislabeling claim survives, Count VI survives even if it is tied to that claim under the ICFA.

* * *

For the above reasons, Church’s motion to dismiss is granted in part and denied in part. Chavez’s claim that Church mispresents the quality of its dietary supplements and labeling on its website is dismissed without prejudice. Chavez’s claims also are dismissed to the extent they are asserted on behalf of any putative class members who did not purchase or consume Vitafusion within Illinois. The Court lacks personal jurisdiction over Church with respect to claims asserted by such consumers and, as a result, any claims asserted on their behalf are denied without prejudice to being reasserted in a court that can exercise personal jurisdiction over the defendant. In all other respects, Church’s motion is denied. A status hearing is set for May 31, 2018.

Date: May 16, 2018



John J. Tharp, Jr.
United States District Judge