IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
GAINESVILLE DIVISION

SUE FAULKNER AND NICOLA TIBBETTS, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, Plaintiffs, v. ACELLA PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 2:22-CV-92-RWS

ORDER

This case comes before the Court on Defendant Acella Pharmaceuticals, LLC's Motion to Strike Class Allegations and to Stay Class Discovery [Dkt. 33]. Acella asks the Court to strike Plaintiffs' class definition and class allegations as proposing an overbroad and fail-safe class. After reviewing the parties' briefs, the Court enters the following Order.

BACKGROUND

Acella is a specialty pharmaceutical company that markets and sells prescription products including NP Thyroid®. NP Thyroid is a prescription medication marketed as a treatment for hypothyroidism. Acella partners with

Allay Pharmaceuticals, a contract manufacturing organization, to produce NP Thyroid. Acella allegedly claims that NP Thyroid is:

> "[m]ade with the highest quality standards under CGMP," (FDA-prescribed rules for making clean and safe medicine), including "[b]atch-to-batch testing to ensure consistent T4 & T3" (the target hormones for thyroid therapy). On the bottles themselves, Acella describes its thyroid pills as "Thyroid Tablets, USP," and—as Acella itself claimed in a lawsuit it filed against a competitor—the "USP" designation is an express representation that the pills meet certain manufacturing requirements.

In May 2020, Acella issued a Class I recall for several lots of NP Thyroid. A Class I recall is issued when there is "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death." In August 2020, the United States Food and Drug Administration also sent a Warning Letter to Acella regarding its "significant violations of current good manufacturing practice ("CGMP") regulations for finished pharmaceuticals." Acella then issued two more Class I recalls for NP Thyroid in September 2020 and April 2021. As part of the recalls, any individual that purchased NP Thyroid from one of the affected lots was offered a refund.

Plaintiffs contend that Ms. Faulkner purchased a 90-day supply of NP Thyroid on or around June 29, 2020, which was subject to Acella's April 2021

recall. And Plaintiffs allege that Ms. Tibbetts was prescribed a separate thyroid medication, but her pharmacy instead filled her prescriptions with NP Thyroid. She therefore purchased NP Thyroid on three occasions, in December 2020, January 2021, and February 2021. Ms. Tibbetts did not know that she was taking NP Thyroid specifically, rather than the medication she was prescribed, until she received a recall letter informing her that the NP Thyroid she purchased and took was adulterated.[1] Both Plaintiffs allege that they subsequently suffered significant symptoms of hypothyroidism and that they were economically damaged by purchasing ineffective NP Thyroid. Plaintiffs state that they have reason to believe that the issues extend beyond the specifically recalled lots.

On May 12, 2022, Ms. Faulkner initially filed suit against Acella on her own behalf and on behalf of a nationwide class of NP Thyroid purchasers [Dkt. 1]. On August 5, 2022, Acella filed a Partial Motion to Dismiss Plaintiff's Complaint, arguing that Ms. Faulkner failed to plead facts showing that "Acella was part of a [RICO] enterprise that engaged in a pattern of racketeering activity" [Dkt. 9]. The

[1] Acella contends that Ms. Tibbetts did not plead that any of the NP Thyroid she consumed was part of a recalled lot, but that contention directly contradicts Ms. Tibbetts' allegation that she received a recall letter informing her that her NP Thyroid was adulterated.

Court granted Acella's Motion, but also granted Ms. Faulkner leave to amend her Complaint if she wished to do so [Dkt. 13].

Accordingly, on May 1, 2023, Ms. Faulkner filed an Amended Complaint, this time with an additional Plaintiff, Nicola Tibbetts, again on behalf of themselves and all others similarly situated [Dkt. 31]. The Amended Complaint asserts claims for fraud (Count 1), statutory strict liability under O.C.G.A. § 51-1-11 (Count 2), negligence (Count 3), breach of express warranty under O.C.G.A. § 11-2-313 (Count 4), breach of implied warranties (Count 5), attorneys' fees under O.C.G.A. § 13-6-11 (Count 6), and punitive damages (Count 7). Plaintiffs seek to represent the following class: "[a]ll natural persons in the United States who purchased NP Thyroid that was not manufactured according to the applicable USP requirements or did not meet those requirements, whether or not Acella recalled the NP Thyroid."

Shortly after the filing of Plaintiffs' Amended Complaint, on May 11, 2023, Acella filed the instant Motion to Strike Class Allegations and to Stay Class Discovery, arguing that Plaintiffs' class allegations and definition should be stricken from the Amended Complaint and the Court should stay class discovery until this Motion is resolved [Dkt. 33]. Plaintiffs opposed Acella's Motion [Dkt. 34], and Acella filed a Reply in support [Dkt. 38].

DISCUSSION

I. Legal Standard

Federal Rule of Civil Procedure 23(c)(1)(A) provides that a court must "[a]t an early practicable time after a person sues or is sued as a class representative . . . determine by order whether to certify the action as a class action." Fed. R. Civ. P. 23(c)(1)(A). There are four prerequisites to class certification as outlined in Rule 23(a):

> (1) the class is so numerous that joinder of all members is impracticable;
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> (2) there are questions of law or fact common to the class;
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> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
>
> (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). The proposed class must also satisfy at least one of the three alternative requirements in Rule 23(b). For example, subsection 23(b)(3) applies when "the questions of law or fact common to class members predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3).

"Generally, a court does not engage in this inquiry until it is presented with the plaintiff's motion for class certification." Carrier v. Ravi Zacharias Int'l Ministries, Inc., 2023 WL 2355891, at *2 (N.D. Ga. Mar. 3, 2023). "In exceptional cases, though, striking or dismissing class allegations is allowed when a defendant demonstrates from the face of the complaint that it will be impossible to certify the class alleged by the plaintiff regardless of the facts the plaintiff may be able to prove." Id. (citations, punctuation, and quotations omitted). Rule 23(d)(1)(D) specifically permits courts to "require that the pleadings be amended to eliminate allegations about representation of absent persons[.]" Fed. R. Civ. P. 23(d)(1)(D). Nevertheless, "[t]his is considered an extreme remedy in the Eleventh Circuit." Carrier, 2023 WL 2355891, at *2 (citation omitted); see also Pettis v. Empire Educ. Grp., Inc., 2019 WL 13215356, at *1 (N.D. Ga. June 11, 2019) ("Although motions to strike class allegations are not categorically improper, they request an extreme remedy that is generally disfavored in the Eleventh Circuit.") (citations and quotations omitted).

II. Analysis

To reiterate, Plaintiffs seek to represent the following class: "[a]ll natural persons in the United States who purchased NP Thyroid that was not manufactured

according to the applicable USP requirements or did not meet those requirements, whether or not Acella recalled the NP Thyroid." [Dkt. 31 – Am. Compl., at ¶ 119].

Acella argues that Plaintiffs' class allegations and class definition should be stricken from the Amended Complaint for several reasons: Plaintiffs' claims are not typical of the majority of the putative class, common questions of law and fact will not predominate over individual issues, and Plaintiffs cannot maintain their improperly alleged "fail-safe" putative class.[2] [Dkt. 33-1 – Mot. to Strike, at 6-15]. Plaintiffs disagree, arguing that they will be able to satisfy the requirements of Federal Rule 23 because their claims raise common issues that can be resolved with common evidence, both named Plaintiffs' claims are typical of the class, common questions of law and fact will predominate, and their case does not present a fail-safe class problem. [Dkt. 34 – Opp. Br., at 8-24].

At the outset, the Court notes that many district courts in the Eleventh Circuit, including this one, have denied motions to strike class allegations as premature at the pleading stage.[3] See, e.g., Sharfman v. Premier Med., Inc., 2021

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[2] Acella also asks that the Court stay class discovery pending resolution of its Motion. [Dkt. 33-1 – Mot. to Strike, at 16-18]. However, since the Court has now ruled on Acella's Motion to Strike, there is no need to stay class discovery and that request is moot.

[3] Federal courts across the country have reached similar conclusions. See, e.g., Glass v. Tradesmen Int'l, LLC, 505 F. Supp. 3d 747, 765 (N.D. Ohio 2020) ("[Defendant] has not demonstrated that [the] class allegations are facially

WL 6884683, at *5 (M.D. Fla. Dec. 29, 2021) ("[T]he issue of whether claims deserve class treatment is a fact-dependent inquiry unsuitable for a motion to dismiss or strike.") (citation, punctuation, and quotations omitted); Mayfield v. Ace Am. Ins. Co., 2020 WL 12029099, at *7 (N.D. Ga. Mar. 19, 2020) ("[T]he class allegations are best tested under Rule 23 on a motion for class certification after the collection and presentation of evidence.") (citation omitted); Chaney v. Crystal Beach Cap., LLC, 2011 WL 17639, at *2 (M.D. Fla. Jan. 4, 2011) ("The shape and form of a class action evolves only through the process of discovery, and it is premature to draw such a conclusion before the claim has taken form.") (citation, punctuation, and quotations omitted). The Court has some inclination to follow that same approach and decline to rule on the substance of this Motion at this stage, because it does not appear from the face of Plaintiffs' Amended Complaint that it will be impossible to certify Plaintiffs' alleged class.

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defective. Deciding whether [class plaintiff] has established commonality and typicality is a question more prudently reserved for a fully briefed class certification motion rather than in the context of a motion to strike class claims at the pleading stage.") (citation and quotations omitted); Davis v. SelectQuote Auto & Home Ins. Servs., LLC, 2023 WL 2885181, at *3 (W.D.N.C. Mar. 10, 2023) ("At this point, it is plausible that Plaintiff could possibly make out a certifiable class, and the undersigned will recommend that issues about whether the class is 'fail-safe' and about ascertainability, commonality, typicality, and adequacy under Federal Rule [] 23 be left to the certification stage.") (citation and quotations omitted).

Nevertheless, because some courts have resolved such motions on their merits and in an effort to be exhaustive and provide some guidance to the parties moving forward, the Court will address Acella's arguments, and Plaintiffs' responses in opposition, in turn.

A. Whether Plaintiffs' Claims Are Typical of the Putative Class

In their Amended Complaint, Plaintiffs state that their claims are typical of other members of the putative class because "each member of the Class suffered a substantially similar economic injury by purchasing Acella's adulterated and worthless NP Thyroid" and "there are no defenses available to [Acella] that are unique to Plaintiffs with respect to their economic damages claim." [Dkt. 31 – Am. Compl., at ¶ 126]. Acella argues that Plaintiffs' claims are not typical of the majority of the putative class because Ms. Faulkner only allegedly purchased sub-potent NP Thyroid from Acella's third recall, and Ms. Tibbetts did not provide a Lot Number that would demonstrate that she purchased NP Thyroid from a recalled lot. [Dkt. 33-1 – Mot. to Strike, at 8]. Accordingly, Acella contends that Plaintiffs' proposed class "would include many individuals who potentially suffered an injury substantially different from that alleged by Plaintiffs or did not suffer any injury *at all*." [Id. at 9 (emphasis in original)]. Plaintiffs naturally reject Acella's argument, reiterating that their "economic loss claims are typical of those

of the class because they both bought adulterated NP Thyroid that was not USP-compliant and was therefore adulterated and worthless," even if those purchases were from different lots. [Dkt. 34 – Opp. Br., at 12]. They further contend that they know that they purchased adulterated and worthless NP Thyroid because both of them received recall letters and public records show that even non-recalled lots did not meet the applicable USP requirements. [Id. at 12-14].

"Typicality measures whether a sufficient nexus exists between the claims of the named representative and those of the class at large." Camafel Bldg. Inspections, Inc. v. Bellsouth Advert. & Publ'g Corp., 2008 WL 649778, at *8 (N.D. Ga. Mar. 7, 2008) (citation omitted). "To satisfy the typicality requirement, a class representative must have the same interest and injury as the class members." Belton v. Ga., 2013 WL 4216714, at *3 (N.D. Ga. Aug. 13, 2013) (citation omitted). "This requirement is satisfied where the named plaintiffs' claims arise from the same event or pattern or practice and are based on the same legal theory as the claims of the class." Id. (citation omitted); see also Camafel Bldg. Inspections, Inc., 2008 WL 649889, at *8 ("A sufficient nexus is established if the claims or defenses of the class and the class representatives arise from the same event and are based on the same legal theory.") (citations omitted). "[T]ypicality does not require identical claims or defenses," and "[f]actual

differences will not render a representative's claim atypical unless the factual position of the representative markedly differs from that of other class members." Camafel Bldg. Inspections, Inc., 2008 WL 649889, at *8 (citations omitted). "The test for typicality is not demanding." In re Synovus Fin. Corp., 2013 WL 12126755, at *5 (N.D. Ga. Mar. 7, 2013) (citation and quotations omitted).

At this stage of the proceedings, the Court finds that Plaintiffs have shown that their claims are typical of the class at large. All that is required is for Plaintiffs to show that their claims "arise from the same event or pattern or practice and are based on the same legal theory as the claims of the class," Belton, 2013 WL 4216714, at *3, and that is what they have done here. Plaintiffs allege that they and all putative class members purchased "Acella's adulterated and worthless NP Thyroid" and suffered economic injury as a result. The fact that Plaintiffs and putative class members purchased NP Thyroid from unique production lots that were part of different recalls or were not recalled at all does not make their claims markedly different. Indeed, class members who purchased NP Thyroid subject to the second recall base their economic loss claims "on the same legal theory" as those who purchased NP Thyroid subject to the third recall, which is that Acella injured them by intentionally selling them defective NP Thyroid.

In addition, it is not clear to the Court what "qualitatively different type[s]" of injuries class members could have suffered, as Acella suggests. [Dkt. 33-1 – Mot. to Strike, at 9-10]. But in any event, that is not a reason to find that typicality is lacking. First, and perhaps most importantly, the only damages that Plaintiffs seek on a class-wide basis are economic damages, attorneys' fees, and punitive damages. [Dkt. 31 – Am. Compl., at ¶¶ 13-14, 160, 181, 187]. Though they acknowledge that "every member of the Class suffered a personal injury to some extent," they make clear that they "do not seek to recover damages for personal injuries on a Class-wide basis. [Id. at ¶ 181; see also id. at ¶ 14 ("Plaintiffs seek to recover for their personal injuries on an individual basis only; they do not seek to represent a personal injury class."); ¶ 160 ("On behalf of themselves only, Plaintiffs also seek to recover for the personal injuries that they suffered. . . ."); ¶ 187 ("Plaintiffs seek to recover for their personal injuries . . . on an individual basis only.")].

Even if Plaintiffs did seek to recover personal injuries on a class-wide basis, that would likely still be permissible "so long as all of the [different] injuries are shown to result from the same practice," as is the case here. Nicholson v. Williams, 205 F.R.D. 92, 99 (E.D.N.Y. 2001) (citation omitted). This Court has reached the same conclusion before, as have many other federal courts across the

country. See, e.g., Civil Rts. Educ. & Enforcement Ctr. v. Hospitality Props. Trust, 317 F.R.D. 91, 105 (N.D. Cal. 2016) ("The fact that some class members may have suffered no injury or different injuries from the challenged practice does not prevent the class from meeting the requirements of Rule 23(b)(2).") (citation and quotations omitted); In re Nat'l Football League Players' Concussion Inj. Litig., 307 F.R.D. 351, 378 (E.D. Pa. 2015) ("Plaintiffs with different injuries can coexist in a class consistent with Rule 23 and Due Process.") (citation omitted); Pyke v. Cuomo, 209 F.R.D. 33, 43 (N.D.N.Y. 2002) ("differences in damages will not destroy typicality," especially where "the injuries were all caused by" the same alleged action) (citation and quotations omitted); Anderson v. Garner, 22 F. Supp. 2d 1379, 1385-86 (N.D. Ga. 1997) (noting that although the plaintiffs and class members "may have suffered different injuries under different circumstances, the nature of the proposed class members' claims remains the same" and the typicality requirement was therefore satisfied.) (citation omitted).

Finally, Acella makes two additional arguments against a finding of typicality, both of which can quickly be rejected. First, it argues that Ms. Faulkner and Ms. Tibbetts' claims are dissimilar because Ms. Faulkner says she bought "sub-potent NP Thyroid" while Ms. Tibbetts contends that her NP Thyroid was "defective," and further that "Plaintiffs may not circumvent the 'typicality'

requirement by lumping all 'USP-noncompliance' together." [Dkt. 38 – Reply Br., at 6-7]. This is, frankly, a distinction without a difference and a bit disingenuous. Acella possesses the testing records showing which lots of its NP Thyroid did not meet USP requirements (and, presumably, by how much). Plaintiffs do not have that information and therefore cannot state with specificity how "USP-noncompliant" their particular NP Thyroid was until they access that information. Regardless, though, the Court does not see how a marginal difference in the level of non-compliance between various production lots would matter here, since typicality does not require *identical* claims and these minor factual distinctions would not alter Plaintiffs' central legal theory.

And second, Acella states that "Plaintiffs' putative class would also include all members who purchased NP Thyroid at someone else's direction or for someone else" and casts doubt that these class members could satisfy the reliance claim necessary for fraud or false representation claims. [Dkt. 33-1 – Mot. to Strike, at 9-10]. As Plaintiffs note, and as Acella does not refute, this Court has rejected such arguments before. See Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1365 (N.D. Ga. 1999) ("[T]he Georgia Supreme Court held the reliance requirement of a fraud claim is satisfied where the defendant intends to defraud the plaintiff, the defendant knows the plaintiff will rely on a third-party, the defendant

fraudulently induces the third-party to act, and the plaintiff relies on the act or actions of the third-party and, as a result, is defrauded.") (citation omitted). The Court sees no reason to disturb that conclusion now, either legally or practically.

Accordingly, the Court concludes that the typicality requirement is satisfied.[4]

B. Whether Common Questions of Law and Fact Will Predominate

Plaintiffs also allege in their Amended Complaint that common questions of law and fact exist as to all putative class members and predominate over any questions affecting only individual class members. [Dkt. 31 – Am. Compl., at ¶ 125]. Plaintiffs detail a series of these such questions, which include "whether NP Thyroid was adulterated or defective because Acella did not use the applicable USP specifications to make it"; "whether the NP Thyroid tablets manufactured, distributed, and sold by [Acella] were adulterated or defective because they failed to meet USP requirements"; "whether [Acella] knew or should have known that the NP Thyroid tablets were adulterated or defective"; "whether adulterated or defective thyroid medication is worthless"; "whether providers, pharmacists, and patients rely on Acella's affirmative USP representations and Acella's related

[4] As with each of Acella's arguments in support of its Motion to Strike, Acella is free to raise this argument again at the class certification stage after the parties have had the opportunity to engage in discovery.

representations regarding the amount of active ingredient when making prescribing and purchasing decisions"; "whether the designation 'Thyroid Tablets, USP' on the pill bottles at issue was false"; "whether Acella's claims of 'batch-to-batch testing' of the pills at issue was false"; "whether Acella's express claims related to CGMP compliance were false"; "whether Acella committed fraud"; and "whether Plaintiff and the Class are entitled to damages, and the proper measure for such damages." [Id.].

Acella disagrees that Plaintiffs' asserted common questions of fact and law would predominate over individual issues. [Dkt. 33-1 – Mot. to Strike, at 10-12]. To the contrary, Acella contends that individualized questions of standing, injury, and liability would predominate, "as individuals who suffered different types of injuries, or no injury at all, would seek a portion of any favorable verdict or settlement," and every "class member's claim would depend on an individual liability determination as to whether the NP Thyroid [each individual] purchased was not manufactured according to the applicable USP requirements or did not meet those requirements." [Id.].

To satisfy the predominant commonality requirement under Federal Rule 23(b)(3), "[a] plaintiff must do more than show that there are common questions of law and fact that exist among potential class members." Gerber v. Delta Airlines,

Inc., 1996 WL 557853, at *3 (N.D. Ga. Aug. 6, 1996). Rather, he or she "must show that common questions predominate over individual issues." Id. That means that "the issues in the class action that are subject to generalized proof, and thus applicable to the class as a whole, must predominate over those issues that are subject only to individualized proof." Bryant v. Mortg. Cap. Res. Corp., 2002 WL 34720249, at *9 (N.D. Ga. May 31, 2002) (citation and quotations omitted). "This rule is important because where common claims do not predominate over individual questions class litigation of any significant size is likely to disintegrate into a myriad of individualized claims, destroying the cohesiveness of the litigation and rendering it entirely unmanageable." Gerber, 1996 WL 557853, at *3 (citation omitted); see also Bryant 2002 WL 34720249, at *9 ("The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation and is far more demanding than Rule 23(a)'s commonality requirement."). (citations and quotations omitted).

Here, the Court finds that common questions of law and fact predominate over questions affecting only individual class members. Indeed, nearly all of the questions that Plaintiffs put forth require determinations and assessments of actions that Acella took (or did not take) and do not depend on any variation in the identity or circumstances of the class members. For example, the issues of "whether Acella

knew or should have known that the NP Thyroid tablets were adulterated or defective," "whether adulterated or defective thyroid medication is worthless," and "whether Acella committed fraud" can and will be resolved on a class-wide basis with generalized proof. Similarly, the issue of "whether the NP Thyroid tablets manufactured, distributed, and sold by [Acella] were adulterated or defective because they failed to meet USP requirements" can be readily proven or disproven through a review of the specifications and testing records that Acella undoubtedly possesses. None of these questions turn or depend on individualized proof.

Nevertheless, Acella's disagreement focuses centrally on supposed "highly-individualized inquiries" into standing and injury, stating that "the Court will have to sort out those plaintiffs who were actually injured from those who were not" and distinguish between different types of injuries. [Dkt. 33-1 – Mot. to Strike, at 11-12]. But as the Court has already noted, Plaintiffs do not seek damages for personal injuries on a class-wide basis and instead only seek economic damages for all putative class members, so to the extent Acella relies on its "varying injuries" argument, that is unavailing. Moreover, the fact that certain class members may have suffered more economic damages than others is insignificant, as those damages can easily be calculated through the use of a formula.

As a result, the Court concludes that the predominant commonality requirement is satisfied.[5]

C. Whether Plaintiffs' Proposed Class Is a Fail-Safe Putative Class

Finally, Acella argues that Plaintiffs' proposed class—persons who purchased NP Thyroid that was not manufactured according to the applicable USP requirements or did not meet those requirements, whether or not Acella recalled the NP Thyroid—would constitute an improper fail-safe class, because membership could not be defined or determined before proving the merits of individual class members' legal claims. [Dkt. 33-1 – Mot. to Strike, at 13-15]. Plaintiffs respond that their class is not fail-safe, and even if it were, the Eleventh Circuit has not determined that such a class is impermissible. [Dkt. 34 – Opp. Br., at 22-24].

"A 'fail-safe' class exists if the class is defined in a way that precludes membership unless the liability of the defendant is established." Cox v. Cmty. Loans of Am., Inc., 2014 WL 1216511, at *14 (M.D. Ga. Mar. 24, 2014) (citations and quotations omitted); see also, e.g., In re Rodriguez, 695 F.3d 360, 370 (5th Cir. 2012) (A fail-safe class occurs when "the class definition is framed as a legal

[5] Once again, Acella can renew this argument at the class certification stage if it chooses to do so.

conclusion.") (citation omitted); Cobb v. Suntrust Bank, 2019 WL 13245235, at *5 (N.D. Ga. Aug. 1, 2019) ("A 'fail-safe' class is an impermissible class definition where a class cannot be defined until the case is resolved on the merits.)" (citation omitted); Snead v. CoreCivic of Tenn., LLC, 2018 WL 3157283, at *15 (M.D. Tenn. June 27, 2018) ("[A] class definition is framed in terms of the defendant's liability and thus creates a fail-safe class when there is statutory language embedded in the class definition, when the verdict is embedded in the class definition, or when there is a reference to a legal right or entitlement.") (citaiton and quotations omitted). Stated differently, "[s]uch a class exists when it includes only those who are entitled to relief." Cobb, 2019 WL 13245235, at *5 (citation omitted). "This definition shields putative class members from receiving an adverse judgment, because by virtue of losing, they are not in the class, and therefore, not bound by the judgment." Id. (citation and quotations omitted).

Some circuit courts have deemed fail-safe classes to be improper for that same reason. See, e.g., Messner v. Northshore Univ. HealthSystem, 669 F.3d 802, 825 (7th Cir. 2012) (finding fail-safe classes to be improper "because a class member either wins or, by virtue of losing, is defined out of the class and is therefore not bound by the judgment.") (citations omitted); Young v. Nationwide Mut. Ins. Co., 693 F.3d 532, 538 (6th Cir. 2012) ("[A] class definition is

impermissible where it is a fail-safe class, that is, a class that cannot be defined until the case is resolved on its merits. . . . Such a class is prohibited because it would allow putative class members to seek a remedy but not be bound by an adverse judgment—either those class members win or, by virtue of losing, they are not in the class and are not bound.") (citation and quotations omitted). Other circuits have explicitly "reject[ed] the fail-safe class prohibition." In re Rodriguez, 695 F.3d at 370.

"The issue of fail-safe classes has not yet been addressed by the Eleventh Circuit." Etzel v. Hooters of Am., LLC, 223 F. Supp. 3d 1306, 1315 (N.D. Ga. 2016) (citation, punctuation, and quotations omitted). However, some lower courts in the Eleventh Circuit have cautioned against the certification of fail-safe classes, critiquing such classes as circular and "assum[ing] what [they] ostensibly seek[] to prove." Id. at 1315-16 (citations and quotations omitted). In addition, the Eleventh Circuit recently warned against the "risk of promoting so-called 'fail-safe' classes." Cordoba v. DIRECTV, LLC, 942 F.3d 1259, 1277 (11th Cir. 2019) (citation omitted).

At this stage, the Court declines to find that Plaintiffs' proposed class is fail-safe. The putative class here includes purchasers of NP Thyroid that was not manufactured according to or did not meet the applicable USP requirements,

whether or not Acella recalled the NP Thyroid in question. This is a factual determination that does not require establishing Acella's liability. Instead, class membership will require establishing two facts, including (1) which of Acella's manufactured lots of NP Thyroid did not meet the applicable USP requirements, and (2) who purchased the products in those lots. These facts may relate to and suggest certain components of liability on Acella's part, but they do not establish liability. Indeed, Plaintiffs and class members will still need to prove the elements of their substantive claims.

For example, to prevail on their fraud claim, Plaintiffs will have to prove that Acella knew that its NP Thyroid was not USP-compliant but intentionally told customers that it was anyway, and that it intended for customers to rely on its false representation. The same is true for Plaintiffs' other claims—Plaintiffs' class definition does not explicitly state or incorporate the elements of those claims, which Plaintiffs will need to prove in order to establish liability. See, e.g., Snead, 2018 WL 3157283, at *16 ("The proposed class would not be a fail-safe class, because the class definition does not reference the defendant's liability" and class members still needed to prove the other elements of their claims); Royal Park Invs. SA/NV v. Wells Fargo Bank, N.A., 2018 WL 739580, at *8 (S.D.N.Y. Jan. 10, 2018) (rejecting challenge that a class of individuals who "were damaged as a

result of" the defendant's alleged conduct was an impermissible fail-safe class); Greenbaum v. KC Jewelry, Inc., 2017 WL 5496224, at *9 (C.D. Cal. Jan. 25, 2017) (distinguishing between class definitions of consumers who were injured by defendants' false advertising and people who purchased jewelry weighing less than indicated on the product label, and finding that the latter did not assume a legal determination and therefore was not fail-safe).

In sum, at least at this stage of the proceedings, the Court finds that Plaintiffs' proposed class definition is not framed as a legal conclusion and does not assume a legal determination, and therefore is not fail-safe. That said, because many courts have held that "a motion to strike class claims is considered premature if the issues raised are the same ones that would be decided in connection with determining the appropriateness of class certification," Acella is welcome to raise this argument again at the class certification stage. Sealock v. Covance, Inc., 2018 WL 2290698, at *1 (S.D.N.Y. May 18, 2018) (citations and quotations omitted); see also, e.g., Tinnin v. Sutter Valley Med. Found., 2022 WL 17968628, at *8 (E.D Cal. Dec. 27, 2022) ("the procedural mechanism of a motion to strike is not the appropriate means for addressing a fail-safe problem."); Soular v. N. Tier Energy LP, 2015 WL 5024786, at *8 (D. Minn. Aug. 25, 2015) ("The Court finds that it

would be premature to dismiss Plaintiff's class allegations at this stage of the litigation" on fail-safe grounds).

CONCLUSION

For the foregoing reasons, Defendant Acella Pharmaceuticals, LLC's Motion to Strike Class Allegations and to Stay Class Discovery [Dkt. 33] is **DENIED**. In addition, because the Court has resolved Acella's Motion to Strike, its Motion to Stay Class Discovery is **DENIED as moot**.

SO ORDERED this 10th day of July, 2023.

RICHARD W. STORY
United States District Judge