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,	)	
vs.	)	No. 2:22-CV-092-RWS
	)	Jury Trial Demanded
ACELLA PHARMACEUTICALS, LLC,	)	
Defendant.	)	

Unopposed Motion for Preliminary Approval of Settlement Class and Memorandum in Support

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Plaintiffs and Defendant Acella Pharmaceuticals, LLC ("Acella"), have reached an agreement (the "Settlement Agreement") that, if approved, will resolve Plaintiffs' class-wide economic loss claims related to the purchase of NP Thyroid. [*See* Ex. 1, January 25, 2024, Declaration of Aaron K. Block ("Block Decl.") at Ex. A.]. Through the Settlement Agreement, Acella has agreed to provide compensation of between $10 and $50 to every person who purchased NP Thyroid nationwide from May 12, 2018, through April 30, 2021, regardless

of whether they had any out-of-pocket expenses or whether the NP Thyroid they purchased was subject to a recall, unless their purchases have already been refunded by Acella or they have requested a refund for any purchase in the class period through a different program (the "Settlement Class"). [*Id.*] The Settlement Class period begins four years before this case was filed—the longest statutory limitations period for Plaintiffs' claims—and ends on the date of publication of Acella's final recall of NP Thyroid. For the reasons set forth below, Plaintiffs respectfully ask the Court to certify the Settlement Class and grant preliminary approval of the parties' Settlement Agreement.

Plaintiffs' Statement of Facts

Plaintiffs' economic loss claims, the subject of the proposed Settlement Agreement, focus on the value of NP Thyroid in light of certain alleged defects. [Dkt. 40 ("Plaintiffs allege that they and all putative class members purchased 'Acella's adulterated and worthless NP Thyroid' and suffered economic injury as a result.")]. Acella makes, markets, and sells NP Thyroid as a prescription treatment for hypothyroidism. [*Id.* at 1]. Acella launched NP Thyroid in 2010 and marketed the drug, which uses animal-derived active pharmaceutical ingredient, as a "natural" alternative to synthetic thyroid medications. [*See*, *e.g.*, Dkt-31-13]. On every bottle label and in related marketing materials, Acella describes NP Thyroid as "Thyroid Tablets, USP,"

which refers to the monograph for "Thyroid Tablets" published by the United States Pharmacopeia ("USP"). [Dkt. 31 ¶ 4].

A USP designation has particular significance as a matter of federal law and pharmaceutical industry norms and expectations. Under the federal Food, Drug, and Cosmetics Act ("FDCA"), a drug is "adulterated" if it "purports to be" a drug recognized in the USP compendium, but "its strength differs from, or its quality or purity falls below, the standard set forth in such compendium." 21 U.S.C. § 351(b). In part because of those legal requirements, USP compliance is an expectation among entities who are responsible for prescribing and dispensing medications; physicians, pharmacists, and commercial drug suppliers expect drugs that claim USP compliance to comply with the USP. Similarly, consumers are entitled to trust that their prescription drugs are what the label says they are. [Dkt. 31 ¶¶ 152–156 (citing FDA statements regarding consumer expectations regarding drug quality in light of drugmaking requirements and norms)]. There is also a baseline expectation that prescription drugs will have the amount of active ingredient on the label, subject to any tolerance recognized in the USP or FDCA.

Further, the FDCA requires prescription drugs to be made according to current good manufacturing practices ("cGMP") and provides that a drug is deemed "adulterated" if it is not made "in conformity with [cGMP] to assure

that such drug meets the requirements of [the FDCA] as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. § 351(a)(2)(B).

The FDA inspected Acella between December 17, 2019, and January 7, 2020. [Dkt. 31-6 (Establishment Inspection Report)]. This inspection and related follow-up activity by the FDA, Acella, and Acella's contract manufacturing organization ("CMO"), Allay Pharmaceuticals, LLC ("Allay"), ultimately led to three recalls of NP Thyroid as well as FDA warning letters to both Acella and Allay. [Dkts. 31-5, 31-19, 31-20, 31-22, and 31-23]. Most pertinent here, the three recalls raised two separate issues related to NP Thyroid's compliance with the requirements of the USP Monograph.

First, the FDA identified that the upper tolerance used to approve lots of NP Thyroid for distribution was too high (i.e., superpotent). As the FDA later explained in its Warning Letter to Acella, "[b]ecause of the narrow therapeutic range of this product, content uniformity is critical and it is especially important to prevent patients with hypothyroidism from receiving insufficient or excessive doses." [Dkt. 31-5]. After the FDA identified this issue, Acella corrected the specifications and recalled lots of NP Thyroid within expiry for which the pre-release test results showed an active ingredient assay result above 110% of the label claim (*i.e.*, all non-expired lots with superpotent test

results). Acella announced this first recall of NP Thyroid on May 21, 2020, recalling thirteen specific lots. [Dkt. 31-20].

Second, independent testing performed by the FDA later in 2020 showed subpotent results. That is, the FDA's testing showed active ingredient assay results below 90% of the label claim, which was below the lower bound of the USP monograph. This also raised a "critical" issue regarding "content uniformity" in a "narrow therapeutic range" drug, but at the other end of the spectrum. [Dkt. 31-5]. The second and third recalls related to the subpotency issue. On September 17, 2020, Acella recalled two lots of subpotent NP Thyroid. [Dkt. 31-22]. On April 30, 2021, FDA published the third and final recall of NP Thyroid. [Dkt. 31-23]. This recall was of thirty-eight specific lots. [*Id.*].

Plaintiffs allege that the manufacturing and testing issues affected all lots of NP Thyroid manufactured by Acella from May 12, 2018, through April 30, 2021, regardless of whether they were subject to the FDA recall. By providing reimbursement for purchasers of *all* NP Thyroid during the Settlement Class period, the Settlement Agreement, discussed further below, goes far beyond the FDA recalls and provides compensation associated with any purchases, including approximately 75% more lots than were covered by the recalls, and it provides individuals who did not participate in the recalls another opportunity to receive compensation.

Procedural History

On May 12, 2022, Plaintiff Sue Faulkner brought the original complaint in this matter, alleging economic loss claims related to the purchase of NP Thyroid on behalf of a nationwide class. [*See generally* Dkt. 1]. As Count One, Plaintiff brought a state law fraud claim, alleging, among other things, that Acella's affirmative misrepresentations regarding USP compliance on at least certain bottles of NP Thyroid constituted actionable fraud as a matter of Georgia law. [*Id.* ¶¶ 110–31]. Plaintiff further alleged that, based on Georgia's unique choice of law rules, Georgia state law governs Plaintiff's fraud and other claims. [*Id.* ¶¶ 124–25, 154–56, and 176–77]. In addition to state law claims, Plaintiff's original Complaint alleged that Acella's and Allay's conduct related to NP Thyroid gave rise to a claim under the federal civil Racketeer Influenced and Corrupt Organizations ("RICO") Act. [*Id.* ¶¶ 132–38].

On August 5, 2022, Acella moved to dismiss Plaintiff's RICO Act claim, raising five different legal issues, which the parties fully briefed. [Dkts. 9, 11, and 12]. On December 22, 2022, this Court entered a twenty-five-page order addressing each of these arguments, accepting two of them, and therefore granting the motion. [Dkt. 13]. Specifically, the Court accepted Acella's arguments that (1) Plaintiff "alleged insufficient facts to show that Acella

conducted a RICO enterprise" that "was separate from its normal business," [*id.* at 15], and (2) Plaintiff "failed to sufficiently allege that Acella engaged in a pattern of racketeering activity," [*id.* at 20].

Although the Court granted Acella's motion to dismiss (while permitting amendment), the Court also made key rulings in Plaintiff's favor, some of which informed the later prosecution of this case. First, in the context of addressing RICO predicate acts, the Court found that Plaintiff plausibly alleged fraud under Rule 9(b)'s heightened pleading standard. [*Id.* at 16 ("The Court finds that Plaintiff alleged sufficient facts to support a finding that Acella committed mail or wire fraud under 18 U.S.C. §§ 1341, 1343.")]. Second, the Court found "that Plaintiff adequately alleged that Acella's fraud caused her and the purported class harm." [*Id.* at 23].

After the Court's ruling on Acella's motion to dismiss, the parties proceeded to discovery. [Dkt. 16 (Plaintiff's Notice of Intent to Proceed on Original Complaint)]. In the parties' Joint Preliminary Report and Discovery Plan, the parties agreed to bifurcated discovery, with an initial phase of litigation focused on class certification and briefing deadlines running through June 7, 2024. [Dkt. 25]. The schedule provides that, after the Court's class certification ruling in late 2024 or 2025, the parties would then meet and confer and propose a new schedule for merits discovery and summary

judgment. [*Id.*]. Under this schedule, a trial would be unlikely to occur before 2026 at the earliest, after merits discovery, summary judgment, and merits *Daubert* proceedings in 2025.

With respect to class discovery, Plaintiff served her first sets of interrogatories and document requests on Acella on the first day on which she was allowed to do so. [Dkt. 23 (L.R. 26.3(A) notice of discovery served February 27, 2023)]. A week later, Plaintiff served a second set of discovery requests on Acella. [Dkt. 26 (L.R. 26.3(A) notice of discovery served March 6, 2023)]. During this same early discovery period, Plaintiff served subpoenas on key third parties with different roles in the distribution chain, including (1) Acella's contract manufacturer, Allay, (2) distributors (*e.g.*, AmerisourceBergen and McKesson), (3) pharmacies (*e.g.*, CVS and Walgreens), (4) Pharmacy Benefits Managers ("PBMs") (*e.g.*, OptumRx and CVS Caremark), and (5) drug linkage databases (*e.g.* First Databank and Elsevier (owner of Gold Standard database)). [Ex. 1, Block Decl. ¶ 10]. Plaintiff also gathered publicly available documents and data from FDA sources, supplementing Plaintiff's pre-suit investigation. [*Id.*].

On May 1, 2023—before Acella produced any documents—Plaintiffs filed their still-operative Amended Complaint. [Dkt. 31 at ¶ 8 n. 10 (describing status of discovery)]. Through this Amended Complaint, Plaintiffs

added a second named plaintiff, Nicola Tibbetts, and revised the proposed class definition to include "[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." [*Id.* at 119]. Plaintiffs did not attempt to re-assert a federal RICO Act claim or otherwise add new claims.

On May 11, 2023, Plaintiffs raised several issues related to Acella's discovery responses via the Court's informal discovery dispute procedures. Also on May 11, 2023, Acella filed a motion to strike Plaintiffs' class allegations. [Dkt. 33]. Through its motion, which Acella argued was "'functionally equivalent to Rule 23 class certification motions' for purposes of the Court's review," Acella argued that Plaintiffs "cannot satisfy Rule 23(a)(3)'s typicality requirement or Rule 23(b)(3)'s predominance requirement." [Dkt. 33-1 at 6–12]. Acella further argued that Plaintiffs sought to represent a "fail-safe" class, and Acella sought a discovery stay until resolution of its motion to strike. [*Id.* at 13–18]. In response, Plaintiffs addressed how they would meet each of Rule 23's requirements. [Dkt. 34 at 8–22].

On July 10, 2023, this Court denied Acella's motion to strike in a twenty-four-page order. [Dkt. 40]. After first noting that the motion could be

summarily denied on procedural grounds, this Court instead addressed the merits "in an effort to be exhaustive and provide some guidance to the parties moving forward." [*Id.* at 6–9]. With respect to typicality, the Court reasoned that "Plaintiffs allege that they and all putative class members purchased 'Acella's adulterated and worthless NP Thyroid' and suffered economic injury as a result," and "[t]he 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." [*Id.* at 11]. With respect to predominance, the Court found that "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." [*Id.* at 17].

The next day—July 11, 2023—the Court resolved the parties' discovery dispute in Plaintiffs' favor. [Dkt. 41]. Through that order, the Court compelled Acella to produce "four categories of documents, including the specifications and manufacturing agreements for NP Thyroid, unredacted copies of its FDA communications related to NP Thyroid's defects, testing records, and sales records," and the Court granted other relief. [*Id.*]. The Court also raised the issue of the statute of limitations *sue sponte*, ordering

Acella to respond "subject to applicable statute of limitations concerns." [Dkt. 41 at 3].

Over the following months, Acella moved forward with the steps it needed to take to comply with the Court's order. To date, Acella has produced approximately 20,000 pages of documents—largely detailed testing and manufacturing records and FDA correspondence—and Acella has produced transactional data going back to the launch of NP Thyroid in 2010. [Ex. 1, Block Decl. ¶ 13]. Acella made its final production on November 15, 2023, and the parties requested and received two extensions to class certification-related discovery deadlines and related motion deadlines to allow Acella to comply with the Court's discovery order. [Dkt. 49 (forty-five day extension); Dkt. 51 (further extension)].

Via third-party subpoenas, Plaintiffs also obtained and evaluated thousands of pages of manufacturing records from Acella's CMO, Allay, as well as data and documents from certain pharmacies, PBMs, distributors, and a linkage database. [Ex. 1, Block Decl. ¶ 10].

While Acella worked to comply with the Court's discovery order, Plaintiffs continued to move forward with third-party discovery and their own expert discovery in support of class certification. Although Plaintiffs had not yet served expert reports before the parties reached the Settlement

Agreement, Plaintiffs had retained six experts, most of whom had either finalized or substantially finalized their class certification reports:

- **FDA/Regulatory:** Grace McNally, Greenleaf Health;
  - 33 years with FDA, including Director, Division of Regulations, Guidance, and Standards within the Office of Policy for Pharmaceutical Quality;

- **Medical:** Dr. James V. Hennessey, MD, Harvard Medical School, Beth Israel Deaconess Medical Center;
  - Co-author of the American Thyroid Association and American Association of Clinical Endocrinologist's Clinical Guidelines for Hypothyroidism in Adults;

- **Pharmaceutical:** Matthew Perri III, PhD, RPh, UGA College of Pharmacy;
  - Professor emeritus of pharmacy and pharmaceutical marketing;

- **USP Testing:** James Bergum, PhD, BergumStats;
  - 40+ years of pharmaceutical industry experience; author of the ASTM Bergum method for compliance testing used by FDA; and

- **Damages:** W. David Bradford, PhD, University of Georgia;
  - Professor of Economics, Busbee Chair in Public Policy;

- **Ascertainability:** Laura Craft, PhD, OnPoint Analytics.

[Ex. 1, Block Decl. ¶ 11]. To date, Plaintiffs have paid these experts approximately $200,000 in connection with their draft class certification reports. [*Id.* ¶ 8].

Notwithstanding the bifurcated nature of the discovery schedule, much of the information and expert opinions developed during class certification

discovery shed light on key merits issues.

At the same time the parties moved forward with class-related fact and expert discovery, they also took the Court's efforts to provide guidance on both merits- and certification-related issues to heart. To that end, in mid-September, Plaintiffs broached the possibility of beginning class settlement discussions. [Ex. 1, Block Decl. ¶ 14]. The parties continued those efforts over the following weeks and months as they also worked toward their discovery deadlines. Among other discussions and efforts, Plaintiffs provided Acella with a confidential presentation that disclosed each of Plaintiffs' experts and their key opinions, calculated Acella's potential exposure at trial, and analyzed the factual basis for Plaintiffs' legal claims both with respect to class certification and the merits, including Plaintiffs' expert-guided analysis of the testing data. [*Id.*].

On December 7, 2023, the Court held a telephone conference in which the parties announced that they had coalesced around a framework for settlement, and the Court provided guidance to the parties. [Dkt. 52]. The Court then stayed "all deadlines until further order of the Court to allow the parties to finalize their settlement agreement." [Dkt. 53]. The parties have now finalized their Settlement Agreement, described below, and move for certification and preliminary approval.

Summary of Settlement

Through the Settlement Agreement, Acella has agreed to reimburse each member of the Settlement Class's out-of-pocket prescription costs, up to the lesser of $50 dollars or a 90-day supply. [Ex. 1, Block Decl. at Ex. A (Settlement Agreement) § 2.A.iii]. Acella has also agreed to pay $10 to members of the Settlement Class who had no out-of-pocket payments for NP Thyroid or if their out-of-pocket payments fall below that amount. [*Id.*]. Settlement Class members are not eligible if (1) they have previously received a refund for any purchase associated with the May 2020, September 2020 or April 2021 recalls or (2) request a refund for any purchase within the class period through a different program.

Based on Plaintiffs' best, good-faith projections of available data, Plaintiffs believe that the Settlement Class contains approximately 1,200,000 members. [Ex. 1, Block Decl. ¶ 15]. After analyzing data regarding out-of-pocket payments for a 90-day supply during the Settlement Class period and applying the $10 minimum and $50 dollar cap, Plaintiffs estimate that the Settlement Agreement makes approximately $41,473,889 in value available to the Settlement Class. [*Id.*].

In addition to this compensation to the Settlement Class, Acella has agreed to pay for all costs related to administration of the Class Settlement.

[Ex. 1, Block Decl. at Ex. A (Settlement Agreement) § II.A.vi]. Acella has also agreed to pay attorneys' fees and costs for the Settlement Class "up to a total of Five Million Dollars ($5,000,000)." [*Id.* § IV].

In exchange for these payments, Acella will receive a release of the Settlement Class's economic loss claims. [*Id.* § III]. The Settlement Agreement acknowledges that Plaintiffs have never brought personal injury claims on a class-wide basis, Plaintiffs' bringing of this action had no effect on the ability of members of the Settlement Class to bring personal injury claims, and the release expressly carves out such claims. [*Id.*]. Consequently, members of the Settlement Class can participate in the settlement and receive compensation for their economic loss claims without releasing any personal injury claims they may have.

The Settlement Agreement sets the following deadlines for notice, final approval, and related events, assuming the final approval hearing remains at the currently scheduled date of May 14, 2024:

Event	Deadline
Deadline for commencement of 60 day notice plan	15 days after entry of Preliminary Approval Order
Last day for Settlement Class Members to object or opt-out to the Settlement	75 days after entry of Preliminary Approval Order
Last day to file Motion for Final Approval of Settlement and Plaintiffs' Petition for Attorneys' Fees and Costs	76 days after entry of Preliminary Approval Order

Settlement Administrator will provide counsel for the Parties with a list of the Opt-Outs	April 23, 2024 (No later than 21 days prior to Final Approval Hearing)
Deadline for Class Counsel to File List of Opt-Outs and respond to any objections Supplemental Declaration from Settlement Administrator reflecting that the Settlement Class Notice Program was executed in accordance with the Preliminary Approval Order	May 7, 2024 (No later than 7 days prior to Final Approval Hearing)
Final Approval Hearing	May 14, 2024
Claims Process Period begins (if settlement approved)	June 1, 2024
Postmark deadline for filing claims	December 1, 2024

Legal Authority and Analysis

"In order to certify [a] settlement class, the Court must examine whether the settlement class complies with Rule 23." *Columbus Drywall & Insulation, Inc. v. Masco Corp.*, 258 F.R.D. 545, 553 (N.D. Ga. 2007) (citing *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 620 (1997). "In addition to complying with Rule 23[], the Court must determine whether the proposed settlement is fair, reasonable, adequate and free of collusion." *Id.* at 558. "In its evaluation of the proposed settlement, the court should be mindful of the judicial policy favoring settlement and cognizant that 'compromise is the

essence of settlement.'" *In re Motorsports Merch. Antitrust Litig.*, 112 F. Supp. 2d 1329, 1333 (N.D. Ga. 2000).

As set out below, the Settlement Class meets all the requirements of Rule 23 and should be certified. Further, the Settlement Agreement is fair, reasonable, adequate, and free of collusion, and the Court should preliminarily approve it.

I. The Settlement Class satisfies Rule 23's requirements.

The Settlement Class "satisfies all the requirements of Fed. R. Civ. P. 23(a) and at least one of the alternative requirements of Rule 23(b)." *Owens v. Metro. Life Ins. Co.*, 323 F.R.D. 411, 415 (N.D. Ga. 2017) (Story, J.). With respect to Rule 23(a), the Settlement Class meets "the prerequisites of numerosity, commonality, typicality, and adequacy of representation." *Id.* With respect to Rule 23(b), Plaintiffs seek certification under "Rule 23(b)(3), which requires 'that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.'" *Id.* (citation omitted). Plaintiffs address each of these requirements in turn.

A. The Settlement Class satisfies numerosity.

"Rule 23 requires that the class be 'so numerous that joinder of all members is impracticable.'" *Luse v. Sentinel Offender Servs.*, No. 2:16-CV-30-RWS, 2017 U.S. Dist. LEXIS 235820, at *8 (N.D. Ga. Aug. 21, 2017) (Story, J.) (citation omitted). While "'[t]here is no single fixed number of Class Members required to meet the numerosity requirement,'" *id.* (citation omitted), the "Eleventh Circuit has noted that 'generally less than twenty-one is inadequate, [and] more than forty [is] adequate,'" *id.* (quoting *American Cast Iron Pipe Co.*, 784 F.2d 1546, 1553 (11th Cir. 1986)).

Here, Plaintiffs estimate that the Settlement Class contains approximately 1.2 million members. The Settlement Class therefore meets the numerosity requirement.

B. The Settlement Class satisfies commonality.

"'Commonality requires that there be at least one issue whose resolution will affect all or a significant number of the putative class members.'" *Carriuolo v. GM Co.*, 823 F.3d 977, 984 (11th Cir. 2016) (quoting *Williams v. Mohawk Indus., Inc.*, 568 F.3d 1350, 1355 (11th Cir. 2009)). "[F]or purposes of Rule 23(a)(2), even a single common question will do." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 359 (2011) (cleaned up; citations omitted). "That common contention, moreover, must be of such a nature that

it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Id.* at 350. "[E]vidence relevant to the commonality requirement is often intertwined with the merits." *Nelson v. United States Steel Corp.*, 709 F.2d 675, 679 (11th Cir. 1983).

Here, the Court previously observed with respect to predominance that "nearly all of the questions that Plaintiffs put forth" in this case "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." [Dkt. 40 at 17]. The same is equally true now with respect to the Settlement Class.

C. The named plaintiffs' claims are typical of the class.

To establish typicality, "there must be a nexus between the class representative's claims or defenses and the common questions of fact or law which unite the class." *Kornberg v. Carnival Cruise Lines, Inc.*, 741 F.2d 1332, 1337 (11th Cir. 1984). "A sufficient nexus is established if the claims or defenses of the class and the class representative arise from the same event or pattern or practice and are based on the same legal theory." *Id.* "In making this determination," the Eleventh Circuit has "concluded that 'a strong similarity of legal theories will satisfy the typicality requirement despite

substantial factual differences.'" *Prado-Steiman v. Bush*, 221 F.3d 1266, 1279 n.14 (11th Cir. 2000) (citation omitted). What matters is "that the named representatives' claims share 'the *same essential characteristics* as the claims of the class at large.'" *Id.* (cleaned up; citation omitted; emphasis in original).

The named plaintiffs' economic loss claims are typical of the Settlement Class because they can show that they purchased NP Thyroid during the Settlement Class period. Because the Settlement Class includes all purchasers of NP Thyroid during a defined period, neither the named plaintiffs nor any other member of the Settlement Class will need to show that they purchased NP Thyroid from a particular lot to be entitled to compensation. Finally, the named plaintiffs, like all other members of the Settlement Class, are not releasing or waiving their personal injury claims.

D. The Settlement Class has been adequately represented.

"'The adequacy of representation prerequisite of Rule 23 requires that the class representatives have common interests with the non-representative class members and requires that the representatives demonstrate that they will vigorously prosecute the interests of the class through qualified counsel.'" *Luse* at *10 (quoting *In re Scientific-Atlanta, Inc. Securities Litig.*, 571 F. Supp. 2d 1315, 1331 (N.D. Ga. 2007)).

Here, the named plaintiffs, Ms. Faulkner and Ms. Tibbetts, have

common interests with the non-representative class members, and they have vigorously prosecuted the interests of the class through qualified counsel. Counsel had no pre-existing relationship with either named plaintiff. [Ex. 1, Block Decl. ¶ 6]. Further, both Ms. Faulkner and Ms. Tibbetts have shown their commitment to prosecuting claims on behalf of the class by fully subjecting themselves to federal discovery, allowing Acella full access to their medical and pharmacy records and responding to detailed discovery requests. [*Id.*].

With respect to counsel, Plaintiffs' attorneys have extensive experience litigating class actions and other complex litigation. This experience includes years of work defending class actions, including product liability and other consumer class actions, defending product manufacturers in scientifically complex litigation, and guiding pharmaceutical companies through FDA inspections and related compliance matters. [Ex. 1, Block Decl. ¶¶ 2–4]. Among other things, Plaintiffs' counsel put this experience to use in this case both in connection with the complex scientific and expert analysis needed to prove Plaintiffs' claims and in connection with the choice-of-law and

jurisdictional analysis necessary to bring the claims on a nationwide basis under Georgia law.

E. Common questions of law and fact will predominate.

"Common issues of fact and law predominate if they 'ha[ve] a direct impact on every class member's effort to establish liability and on every class member's entitlement to injunctive and monetary relief.'" *Williams*, 568 F.3d at 1357. Predominance "does not . . . require each and every issue be susceptible of common proof." *Owens*, 323 F.R.D. at 419. "Certification is proper when 'one or more of the central issues in the action are common to the class and can be said to predominate' 'even though other important matters will have to be tried separately, such as damages or some affirmative defenses peculiar to some individual class members.'" *Id.* (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016)).

As noted above, this Court previously held that "nearly all of the questions that Plaintiffs put forth" in this case "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." [Dkt. 40 at 17]. Here, Plaintiffs believe the evidence that Acella produced pursuant to the Court's discovery order, [Dkt. 41], provides a basis for establishing common proof of the claims of the Settlement Class. And, because the

Settlement Agreement compensates members of the Settlement Class regardless of whether they can establish an associated lot number, the Settlement Agreement eliminates a potentially individualized issue that the parties may have otherwise litigated. [*cf.* Dkt. 41 (referring to discovery "necessary to determine which of Acella's NP Thyroid lots did not meet applicable USP requirements and who purchased NP Thyroid from those lots and is therefore entitled to be a member of Plaintiffs' putative class")].

F. The Settlement Class satisfies superiority.

In addition to predominance, the "second part of Rule 23(b)(3) requires that Plaintiffs establish that a class action is 'superior to other available methods for fairly and efficiently adjudicating the controversy.'" *Luse*, 2017 U.S. Dist. LEXIS 235820, at *12 (quoting Fed. R. Civ. P. 23(b)(3)). "In weighing the relative advantages of a class action, courts consider what is 'realistically available to plaintiffs.'" *Id.* (quoting *Klay v. Humana, Inc.*, 382 F.3d 1241, 1269 (11th Cir. 2004)).

Here, a class action is superior to other available methods to litigate the Settlement Class's economic loss claims. For each individual member of the Settlement Class, bringing a lawsuit for the purchase price of NP Thyroid would not be worth the cost of litigation, and "requiring each Class Member to adjudicate a separate claim would be 'repetitive, wasteful, and an

extraordinary burden on the courts.'" *Id.* at *15 (citation omitted). Resolving these claims through this class action is therefore superior.

Members of the Settlement Class are not giving up any personal injury or wrongful death claims they may have. To the extent any member of the Settlement Class believes that they have such claims, they can still file an individual action seeking related damages in an appropriate forum, and this class action will have had no effect on their ability to bring such claims, subject to any valid statute of limitations defense or other defenses Acella may have. For the economic loss claims resolved by the Settlement Agreement, however, there is no question that class resolution is superior.

II. The Settlement Agreement is fair and reasonable and should be approved.

"In addition to complying with Rule 23[], the Court must determine whether the proposed settlement is fair, reasonable, adequate and free of collusion." *Columbus Drywall*, 258 F.R.D. at 558. "Relevant factors include '(1) the likelihood of success at trial; (2) the range of possible recovery; (3) the range of possible recovery at which a settlement is fair, adequate, and reasonable; (4) the anticipated complexity, expense, and duration of litigation; (5) the opposition to the settlement; and (6) the stage of proceedings at which the settlement was achieved.'" *Luse*, 2017 U.S. Dist.

LEXIS 235820, at *16 (quoting *Faught v. Am. Home Shield Corp.*, 668 F.3d 1233, 1240 (11th Cir. 2011)).

"In considering the settlement, the district court may rely upon the judgment of experienced counsel for the parties," and, "[a]bsent fraud, collusion, or the like, the district court 'should be hesitant to substitute its own judgment for that of counsel.'" *Nelson v. Mead Johnson & Johnson Co.*, 484 F. App'x 429, 434 (11th Cir. 2012) (citations omitted). "It has been repeatedly recognized that settlements are 'highly favored in the law and will be upheld whenever possible because they are means of amicably resolving doubts and preventing lawsuits,'" and "[s]ettlements in class action cases are also favored because they 'conserve judicial resources by avoiding the expense of a complicated and protracted litigation process.'" *Hillis v. Equifax Consumer Servs.*, Nos. 1:04-CV-3400-TCB, 1:07-CV-314-TCB, 2007 U.S. Dist. LEXIS 48278, at *28 (N.D. Ga. June 12, 2007) (citations omitted; cleaned up).

As shown below, the Court should approve the Settlement Agreement after considering the relevant factors identified by the Eleventh Circuit.

A. The likelihood of success at trial.

Although Plaintiffs believe that they would ultimately prevail at trial, the road there is long. Acella has raised ninety separate defenses in this action. [Dkt. 32 at 64–89]. By and large, these "factual and legal defenses

have not been tested." *Luse*, at *17. But Acella has shown that it will vigorously defend itself at every stage of the litigation. Acella retained highly experienced and qualified class action defense counsel, Acella has already litigated a partially successful motion to dismiss and an unsuccessful motion to strike, and Acella actively contested the scope of discovery during the class certification stage of the case. Absent settlement, Acella would no doubt continue this robust defense through class certification, class *Daubert* motions, merits discovery, summary judgment, merits *Daubert* motions, and trial.

To win at trial, Plaintiffs would need to successfully navigate every issue raised by Acella. Further, because a class has not yet been certified, the scope of the class claims that would ultimately go to trial (if any) is uncertain, both in terms of class membership and claims. At this stage of the litigation, the only certainty is that getting to trial from this point would take years, and it would require success on all issues and defenses.

B. The range of possible recovery.

"In determining whether a settlement is fair and reasonable, the court must also examine the range of possible damages that plaintiffs could recover at trial and combine this with an analysis [of] plaintiffs' likely success at trial to determine if the settlements fall within the range of fair recoveries."

Columbus Drywall, 258 F.R.D. at 559. "The 'challenge Plaintiffs would face, if their claims did survive on the merits, in proving damages,' is a factor the Court may consider in evaluating the range of potential damages." *Luse* 2017 U.S. Dist. LEXIS 235820, at *18 (quoting *Greco v. Ginn Development Co.*, 635 F. App'x 628, 632 (11th Cir. 2015).

The amount of damages Plaintiffs would recover through trial is uncertain. At trial, Plaintiffs would seek to prove that all NP Thyroid sold through the third recall was adulterated and worthless because the lots were made with inappropriate specifications and insufficient quality control. [Dkt. 41 at 11 ("Plaintiffs allege that they and all putative class members purchased 'Acella's adulterated and worthless NP Thyroid' and suffered economic injury as a result.")]. Acella would likely contest that theory, and would be expected to argue, *inter alia*, that, even if Plaintiffs were economically damaged, the NP Thyroid they purchased had some therapeutic benefit and had an economic value above zero. The parties would likely also dispute the number of lots of NP Thyroid that were outside of USP potency specifications, which was a focal point of Plaintiffs' discovery investigation and expert analysis.

For damages during the Class Period, Plaintiffs estimate that they would seek damages as high as $294 million at trial, including both out-of-

pocket payments ($178M) and insurance payments ($116M) under Georgia's collateral source rule. However, in contrast to multinational pharmaceutical companies, a mid-sized, specialty pharmaceutical producer like Acella would not have the finances to fully reimburse every purchase of its flagship product. Thus, even the biggest possible trial "win" for Plaintiffs would likely be somewhat illusory as a practical matter, and it could take years and multiple post-verdict proceedings for class members to receive compensation. At the other end of the spectrum, the jury could find for Acella, or it could find for Plaintiffs in an amount far below the full purchase price of each bottle of NP Thyroid sold during the relevant period.

C. The Settlement Agreement is within the range of possible recovery at which settlement is fair, adequate, and reasonable.

"In assessing [] settlements, the Court must look to the range of possible damages that Plaintiffs could recover at trial and then combine this assessment with the likelihood of Plaintiffs' success at trial to determine whether the settlements fall within the range of recoveries that is fair." *In re Motorsports*, 112 F. Supp. 2d at 1334. "To determine whether a proposed settlement falls within the range of reasonableness, a court must analyze the total value to the settlement class." *Columbus Drywall*, 258 F.R.D. at 559. "Settlements have been approved where they provided far less than the

damages that plaintiffs could possibly recover at trial." *Luse*, 2017 U.S. Dist. LEXIS 235820, at *19 (collecting cases approving settlements as low as 10% of the potential trial recovery).

Here, the Settlement Agreement is a claims-made settlement. For purposes of valuation, "'[a] claims-made settlement is . . . the functional equivalent of a common fund settlement where the unclaimed funds revert to the defendant'; indeed, the two types of settlements are 'fully synonymous.'" *Poertner v. Gillette Co.*, 618 F. App'x 624, 628 n.2 (11th Cir. 2015) (citation omitted). "A settlement's fairness is judged by the opportunity created for the class members, not by how many submit claims. What matters is the settlement's value to each class member—it is ultimately up to class members to participate or not." *Hamilton v. SunTrust Mortg. Inc.*, No. 13-60749-CIV-COHN/SELTZER, 2014 U.S. Dist. LEXIS 154762, at *19 (S.D. Fla. Oct. 24, 2014); *see also*, *e.g.*, *In re Blue Cross Blue Shield Antitrust Litig. MDL 2046*, 85 F.4th 1070, 1100 (11th Cir. 2023) (holding that courts must evaluate the value of common funds by the amount of the "fund established for the benefit of the class"); *Carter v. Forjas*, 701 F. App'x 759, 767 (11th Cir. 2017) (rejecting argument that settlement should be evaluated based on "the amount actually paid to the class" and counting full $30 million maximum payout in capped claims made structure toward the settlement value);

Poertner, 618 F. App'x at 630 (holding that it is a "flawed valuation" to "limit[] the monetary value [of a claims made settlement] to the amount of [the defendant's] actual payments to the class").

Further, because the parties separately negotiated a cap on the attorneys' fees that Plaintiffs' counsel may request—and those fees do not come directly out of a class fund—the Settlement Agreement's value should be calculated according to Eleventh Circuit authority governing "constructive common funds." "The rationale for the constructive common fund is that the defendant negotiated the payment to the class and the payment to counsel as a 'package deal.'" *Ne. Eng'rs Fed. Credit Union v. Home Depot, Inc. (In re Home Depot, Inc., Customer Data Sec. Breach Litig.)*, 931 F.3d 1065, 1080 (11th Cir. 2019). "The defendant is concerned, first and foremost, with its total liability," and "defendants undoubtedly take into account the amount of attorney's fees when they agree on an amount to pay the class." *Id.* (citations omitted). Thus, where the parties negotiate a separate amount in attorneys' fees that does not come directly out of the class compensation, "'the sum of the two amounts ordinarily should be treated as a settlement fund for the benefit of the class, with the agreed-on fee amount constituting the upper limit on the fees that can be awarded to counsel.'" *Id.* (citation omitted).

Applying this authority, Plaintiffs' best estimate is that the Settlement Agreement secures a value for the Settlement Class of approximately $46,473,889. This value consists of approximately $41,473,889 made available to the class through the claims process, plus a negotiated cap on Plaintiffs' forthcoming request for attorneys' fees and litigation expenses of $5,000,000.[1]

The value provided by the Settlement Agreement falls well within the range of possible recovery. As addressed above, Plaintiffs are still years away from trial, and it remains possible that Plaintiffs could receive no recovery or a disappointing recovery. Even compared to a best-case scenario at trial—a scenario that would likely leave Plaintiffs with a partially unrecoverable

[1] Applying the formula mandated by the Eleventh Circuit for constructive common fund settlements, the agreed $5,000,000 cap on attorneys' fees is approximately 10.8% of the total class benefit. *Ne. Eng'rs Fed. Credit Union v. Home Depot, Inc. (In re Home Depot, Inc., Customer Data Sec. Breach Litig.)*, 931 F.3d 1065, 1092 (11th Cir. 2019) ("In mathematical terms, the equation for the percentage method in constructive common-fund cases effectively works like this: the actual payment to counsel is the product of (1) the percentage the court decides to award, and (2) the payment to the class plus the *expected* payment to counsel (together, the class benefit).") (emphasis in original). As Plaintiffs will detail in their fees petition, the agreed fee would be "presumptively reasonable" even if it were twice as high, and the negotiated cap prevents Plaintiffs from requesting a "typical[]" fee award "of 20 to 30 percent." *In re Blue Cross Blue Shield*, 85 F.4th at 1100.

judgment—the settlement value exceeds 15% of the trial damages estimate. This factor therefore weighs in favor of approval.

D. The anticipated duration, expense, and complexity of litigation.

With respect to both the facts and the law, this case is extremely complex. On the facts, the case involves technical issues related to the manufacturing, marketing, and distribution of a prescription drug. Litigating the case required Plaintiffs to develop an understanding of highly technical issues, including the analysis of thousands of pages of testing records, and to apply their understanding of a highly regulated area of manufacturing. On the law, Plaintiffs bring a nationwide class action under Georgia law, asserting a fraud theory that requires Plaintiffs to prove third-party reliance and navigate the learned intermediary doctrine and a variety of other defenses.

Given the level of complexity, the parties agreed to a bifurcated schedule that had the effect of pushing the trial date far into the future. Under the schedule, the depositions of Plaintiffs' six class-certification-related experts, the disclosure of Acella's class experts and their depositions, any rebuttal reports, and class certification and related *Daubert* briefing were set to run through July 26, 2024. [Dkt 51]. It is unlikely that the Court would

rule on class certification until late 2024 at the earliest. The parties would then begin full merits discovery—a process involving a substantial ESI review and production—in 2025, with merits expert discovery, summary judgment, and merits *Daubert* motions all to be decided before the potential trial of this matter in 2026 or later.

By the time this case went to trial, Plaintiffs anticipate that each of the parties would have incurred well over $1,000,000 in expert fees and other litigation costs. It would also take the parties thousands of additional attorney hours to bring this case through class certification, merits discovery, summary judgment, and trial.

E. Opposition to the settlement.

Because the Settlement Class has not yet received notice of the Settlement Agreement, it is somewhat premature to address this consideration. However, Acella informed Plaintiffs during the negotiation process that Acella has been in communication with two state attorneys general, and Acella represents that they are both aware of the planned settlement and have voiced no objection based on their understanding. [Ex. 1, Block Decl. ¶ 17].

F. The stage of proceedings at which settlement was reached.

The parties have vigorously litigated this case for more than a year-and-a-half, and Plaintiffs' counsel evaluated the claims, securing third-party documents and engaging multiple experts, for approximately six months before filing suit. [Ex. 1, Block Decl. ¶¶ 7–13]. Still, the action is in its relatively early stages. When the Court stayed all pending deadlines, Plaintiffs had substantially completed but not yet served affirmative expert reports supporting class certification. [Ex. 1, Block Decl. ¶ 12].

While there would be a long way still to go in this case absent settlement, Plaintiffs also received discovery necessary to evaluate the scope of the class, understand key issues and documents regarding the merits, and analyze potential damages. The Court compelled the production of certain of this discovery, [Dkt. 41], and Plaintiffs also received substantial productions of documents and data from third parties.

The parties' ability to reach resolution this early in the case is a strong factor supporting approval, and it advances the well-recognized purpose of class action settlements to conserve judicial resources. Indeed, the parties' ability to reach an early resolution was due in large part to the detailed guidance provided by the Court across more than fifty pages of orders.

The Settlement Agreement is fair, reasonable, adequate, and free of collusion, and Plaintiffs ask the Court to preliminarily approve it.

III. The proposed class notice plan should be approved.

Following preliminary approval, Rule 23(e)(1) requires that the Court "direct notice in a reasonable manner to all class members who would be bound by the proposal . . . ." That notice "must contain information reasonably necessary to make a decision to remain a class member and be bound by the final judgment or opt out of the action." *In re HealthSouth Corp. Sec. Litig.,* 334 F. App'x 248, 254 (11th Cir. 2009) (internal quotation marks omitted).

As set out below, both the manner and form of notice comply with the requirements of Rule 23 and Due Process. Plaintiffs ask the Court to approve the parties' Notice Plan and appoint KCC Class Action Services, LLC ("KCC") as administrator of the Notice Plan.

A. The Notice Plan.

The Parties jointly selected, and Acella has retained, KCC to disseminate Notice and implement the Settlement following Final Approval. Notice will begin no later than 15 days after entry of a Preliminary Approval Order and will conclude 75 days after entry of a Preliminary Approval Order. [*See* Ex. 2, January 24, 2024, Declaration of Carla A. Peak Regarding

Settlement Notice Plan ("Peak Decl.") at ¶ 13 (describing notice runtime); *see also* Ex. 1, Block Decl. at Ex. A (Settlement Agreement) § VI.A (describing notice start date). The Notice Plan is designed to reach approximately 70% or more of likely Settlement Class Members. [Ex. 2, Peak Decl., ¶ 8].

The Notice Plan utilizes paid digital notice guided by MRI-Simmons/Comscore data and other research, with highly targeted digital banner and newsfeed advertisements that will be placed on a variety of websites and the social media platform Facebook, allowing for multiple impressions to be delivered to likely Settlement Class Members, directing them to be instantly delivered to the settlement website. [Ex. 2, Peak Decl., ¶ 11]. The digital media campaign will consist of approximately 166,500,000 impressions distributed programmatically to target adults 18 years of age or older nationwide, with additional emphasis to women 45 years of age or older who are more likely to suffer from hypothyroidism, and some impressions will appear alongside content related to thyroid conditions where available. [*Id.* ¶¶ 12–13]. The advertisements will appear on both desktop and mobile devices (tablets and smartphones). [*Id.* ¶ 13]. Notice of the settlement will also be published on Acella's website and Plaintiffs' website. [*Id.* ¶ 14; *see also* Ex. 1, Block Decl. at Ex. A (Settlement Agreement) § VI.A].

The Notice Plan is designed to provide Settlement Class Members with important information about the Settlement and their rights, including the Opt-Out, Objection, and Claims deadlines; the means by which Settlement Class Members may submit Claim Forms and the supporting documents required to make a valid claim; the date on which the Final Approval Hearing is scheduled to occur; Frequently Asked Questions and other Settlement related documents and information. [Ex. 2, Peak Decl., ¶ 8].

B. KCC is qualified to serve as administrator of the Notice Plan.

The Parties' nominated Claims Administrator, KCC, is particularly qualified to administer this Settlement. KCC provides comprehensive class action services, including claims administration, legal notification, website design, call center support, class member data management, and other related services critical to the effective administration of consumer class action settlements. [Ex. 2, Peak Decl., ¶ 3]. KCC has administered class action settlements and notice plans in thousands of cases, including a variety of consumer matters, as well as matters involving prescription drugs, including: *Barba v. Shire U.S., Inc.*, No. 1:13-cv-21158 (S.D. Fla.); *Cicciarella v. Califia Farms, LLC*, No. 7:19-cv-08785 (S.D.N.Y); *Crane v. Sexy Hair Concepts, LLC*, No. 1:17-cv-10300 (D. Mass.); *Elkies v. Johnson & Johnson*

Services, Inc., No. 2:17-cv-07320 (C.D. Cal.); *Friend v. FGF Brands (USA), Inc.*, No. 1:18-cv-07644 (N.D. Ill.); *In re Hypodermic Products Antitrust Litig.*, MDL No. 1730, No. 2:05-CV-01602 (D. N.J.); *In re Morning Song Bird Food Litig.*, No. 3:12-cv-01592 (S.D. Cal.); *In Re: Rust-Oleum Restore Marketing, Sales Practices and Products Liability Litig.*, No. 1:15-cv-01364 (N.D. Ill.); *In re: Skelaxin (Metaxalone) Antitrust Litig.*, No. 1:12-md-02343 (E.D. Tenn.); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, (Direct Purchasers), No. 1:14-md-02503 (D. Mass.); *In re Thalomid and Revlimid Antitrust Litig.*, No. 2:14-cv-06997 (D. N.J.); *In re Trader Joe's Tuna Litig.*, No. 2:16-cv-01371 (C.D. Cal.); *Khan v. BooHoo.com USA, Inc.*, No. 2:20-cv-03332 (C.D. Cal.); *Poertner v. The Gillette Co. and The Procter & Gamble Co.*, No. 6:12-CV-00803 (M.D. Fla.); *Rikos v. The Procter & Gamble Co.*, No. 1:11-cv-00226 (S.D. Ohio); *Suchanek v. Sturm Foods, Inc.*, No. 3:11-cv-00565 (S.D. Ill.); and *Worth v. CVS Pharmacy, Inc.*, No. 2:16-cv-0200498 (E.D.N.Y.). [*Id.* ¶ 6]. The Court should appoint KCC as Claims Administrator for the Settlement.

C. The proposed Notice Plan complies with Rule 23.

The parties' proposed Notice Plan provides the best notice practicable and complies with due process and the criteria of Rule 23. [Ex. 2, Peak Decl., ¶ 19]. The proposed summary notices and long-form notice would be in substantially the same form as Exhibits 2 and 3 to the Settlement

Agreement. *See* Ex. 1, Block Decl. at Ex. A (Settlement Agreement) at Exs. 2 and 3. The summary notice will inform Settlement Class members of the substantive terms of the Settlement Agreement, including, among other things: the nature of this case and the Plaintiffs' claims; the terms of the proposed settlement; how to make a claim for benefits of the settlement, if it is approved; how to object to the settlement or opt out of the class; the existence of class and the provision for payment of attorneys' fees in the settlement; the hearing this Court will hold for final approval of the settlement; and how class members can obtain a long-form notice with more information about the settlement. [*Id.*]. The proposed notices provide more than sufficient information to allow Settlement Class Members to determine how to proceed with respect to the Settlement and meet the requirements of due process. Thus, the Court should approve the Notice Plan, including the form and content of the notices.

Conclusion

For the foregoing reasons, the Court should certify the Settlement Class, preliminarily approve the Settlement Agreement, and approve the class Notice Plan.

Respectfully submitted this 2d day of February, 2024.

THE BLOCK FIRM LLC

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CERTIFICATE OF SERVICE

I certify that I filed the foregoing via the Court's CM/ECF system on February 2, 2024, which will serve notice on all parties.

/s/ Aaron K. Block
Aaron K. Block

CERTIFICATE OF TYPE STYLE AND SIZE

I certify that the style and size of type used in this document is Century Schoolbook 13 point.

/s/Aaron K. Block
Aaron K. Block