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

SUE FAULKNER, on behalf of herself and all others similarly situated,	)	
Plaintiff,	)	
vs.	)	No. 2:22-CV-092-RWS
	)	Jury Trial Demanded
ACELLA PHARMACEUTICALS, LLC,	)	
Defendant.	)	

Complaint

---

1. Plaintiff brings this action on behalf of herself and all others similarly situated against Defendant Acella Pharmaceuticals, LLC ("Acella" or "Defendant").

Introduction

2. For years, Acella has used false representations to sell its thyroid medication, NP Thyroid. Since at least February 2019, Acella has touted 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.[1] And the pill bottles expressly represent that each pill contains a specific amount of active ingredient. But none of that is true.

3. The truth is that the FDA has cited Acella for quality control issues going back to at least 2012. Despite being on notice for years that its quality control was insufficient, an FDA inspection in late 2019 and early 2020 concluded that "[t]here is ***no quality control unit***" at Acella.[2] The FDA also found "significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals."[3] Despite Acella's claims of "[b]atch-

---

[1] *See generally*, Exhibit 1, Acella's Amended Complaint in *Acella Pharm., LLC v. Westminster Pharm., LLC*, No. 1:18-CV-247-CAP ("*Acella v. Westminster*"), dkt. 44.

[2] Exhibit 2, Form FDA 483 related to December 2019 and January 2020 inspection of Acella (emphasis added).

[3] Exhibit 3, August 14, 2020 FDA Warning Letter to Acella ("Acella Warning Letter"), (also accessible at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/acella-pharmaceuticals-llc-604438-08142020) (last accessed May 9, 2022).

to-batch" testing, the truth is that Acella only reviewed "the final product testing packet" from one of its associated manufacturers "of less than 1%" of NP Thyroid, and Acella did not do anything to "review[] the integrity of the . . . results"—that is, Acella did not do any testing itself and failed to ensure that its drugs actually were properly manufactured.[4]

4. As a result of these and other issues, Acella consistently and knowingly sold defective products, including continued sales of defective NP Thyroid after Acella received multiple citations and a formal warning letter from the FDA for selling adulterated and unapproved drugs.

5. Between May 22, 2020 and April 30, 2021, Acella issued three recalls of NP Thyroid. The first was for "super-potent" thyroid medication—pills in which the amount of active ingredient exceeded the amount listed on the bottle by an unsafe amount. The second was for two lots of "sub-potent" thyroid medication—pills in which the amount of active ingredient was below the amount promised on the bottle by an unsafe amount. The third recall was for thirty-eight lots of sub-potent thyroid medication with manufacturing dates ranging from March 4, 2020 through March 16, 2021. Each of these

[4] Exhibit 4, Establishment Inspection Report for the FDA's December 2019 through January 2020 inspection of Acella ("EIR").

recalls was a "Class I recall," which is the most serious kind involving "a situation in which there is a reasonable probability that the use of or exposure to a violative product"—here NP Thyroid—"will cause serious adverse health consequences or death."[5] Collectively, Acella acknowledged approximately 50 serious adverse events linked to those defectively manufactured drugs—and there were likely more defective lots that went undetected due to Acella's documented issues related to testing and quality control.

6. Plaintiff was a victim of Acella's conduct. Plaintiff purchased NP Thyroid in reliance on Acella's representations. Indeed, because prescribing decisions for thyroid medication are directly based on the amount of active ingredient in the pills, everyone in the chain of distribution—from physicians to pharmacists to patients—necessarily relied on Acella's express representation that its NP Thyroid medication contained the amount of active ingredient written on the bottle. But NP Thyroid that Plaintiff purchased and used was defective and was part of at least one recall; the representations that Acella made to Plaintiff were false.

[5] Exhibit 5, FDA webpage titled Recalls Background and Definitions (also accessible at: https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions) (last accessed May 9, 2022).

7. Plaintiff was damaged by buying defective pills. "Because of the narrow therapeutic range of [NP Thyroid], content uniformity is critical and it is especially important to prevent patients with hypothyroidism from receiving insufficient or excessive doses."[6]

8. Plaintiff's damages—and the relief she seeks—come in two forms. First, Plaintiff was economically damaged by purchasing NP Thyroid that was worthless. On behalf of herself and a nationwide class of purchasers (the "Class," as further defined below), Plaintiff seeks to recover the full purchase price of all defective NP Thyroid that Acella sold in the United States. Plaintiff and the Class further seek treble damages and attorneys' fees through certain of their claims.

9. Second, Plaintiff was personally injured by Acella's subpotent thyroid pills. While taking Acella's subpotent medication—but before Acella initiated the third recall and announced that patients should avoid defective NP Thyroid pills—Plaintiff began experiencing significant symptoms of hypothyroidism, including hair loss, extreme fatigue, painful sensitivity to temperature changes, and debilitating hives. Plaintiff has been working with her providers to try to restore her thyroid levels to normal following these

[6] Exhibit 3, Acella Warning Letter.

events and address the related complications, but it has been a long, painful, and expensive process. Plaintiff seeks to recover for her personal injuries on behalf of herself only; she does not seek to represent a personal injury class.

10. As set out below, Plaintiff brings claims under several theories—including strict liability, warranty, common law fraud, and RICO—to recover for the wrongful conduct of Acella and its associates.

Jurisdiction and Venue

11. The Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a) and (d). Plaintiff is a citizen of New York. According to the FDA's inspection reports, Acella is ultimately owned by trusts and appears to be, through the owners of those trusts, a citizen of a state other than New York—most likely, Georgia. (It may be necessary for the Court to require Acella to disclose the identity of its ultimate owners to ensure diversity as between Ms. Faulkner and Acella.) The amount in controversy exceeds $75,000. As between the putative class and Acella, there is diversity pursuant to § 1332(d) because at least one class member is a citizen from a state other than Georgia and the amount in controversy exceeds $5,000,000.

12. The Court also has original subject-matter jurisdiction under 28 USC 1331 because Plaintiff and the Class bring a federal statutory claim

under the civil remedies provision of the federal RICO Act, 18 U.S.C. § 1964(c).

13. The Court has personal jurisdiction over Acella pursuant to Federal Rule of Civil Procedure 4(k)(1) because Acella is headquartered in Georgia and because Acella's conduct giving rise to this controversy occurred in the Northern District of Georgia.

14. Venue is proper in the Court's Gainesville Division because a substantial part of the events and omissions giving rise to the controversy occurred in that division—specifically at Acella's headquarters in the part of Alpharetta that is in Forsyth County. *See* 28 U.S.C. § 1391(b)(2); N.D. Ga. L.R. 3.1(B)(1)(a).

Parties

15. Plaintiff, Ms. Faulkner, is a citizen of New York who resides in Suffolk County, New York. Plaintiff was prescribed, purchased, and consumed NP Thyroid manufactured and distributed by Defendant Acella. Among other purchases, on or around June 29, 2020, Plaintiff bought a 90-day supply of NP Thyroid 60 milligram tablets, which bore the NDC number 68102007, Lot Number M330K19-9. When purchasing NP Thyroid from Defendant, Plaintiff reviewed the accompanying labels and disclosures and

understood them as representations and warranties by Acella that the medications were properly manufactured and contained the appropriate level of thyroid. Plaintiff relied on these representations and warranties in deciding to purchase NP Thyroid, and these representations and warranties were part of the basis of the bargain, in that she would not have purchased NP Thyroid from Defendant if she had known that the pills were not, in fact, properly manufactured and were subpotent.

16. Defendant, Acella, is a Delaware LLC with its principal place of business at 1880 McFarland Parkway, Suite 110, Alpharetta, Georgia 30005. According to Acella's filings in other cases, Acella's only member is Acella Holdings, LLC, whose only member is Alora Pharmaceuticals, LLC. Alora is apparently wholly owned by various trusts. The identities of the owners and trustees of those trusts is private information held by Acella and its owners, but, on information and belief, Ms. Faulker alleges that they are not citizens of New York given Acella's ties to Georgia.

Factual Allegations

Acella's Formation and the Launch of NP Thyroid

17. Acella was founded in 2007 and holds itself out to the public as "a specialty pharmaceutical company committed to . . . bringing quality, affordable products to customers and patients."[7]

18. Acella launched its NP Thyroid product in October 2010.

19. Acella makes, markets, and sells NP Thyroid, which is a medicine intended for the treatment of hypothyroidism. NP Thyroid's active ingredients are levothyroxine (tetraiodothyronine sodium) and liothyronine (liothyronine sodium), which are generic prescription medications indicated as a replacement or supplemental therapy in patients with hypothyroidism, among other conditions.

20. Acella represents that its NP Thyroid tablets contain 38 mcg levothyroxine (T4) and 9 mcg lithyronine (T3) per each 60-miligram tablet.[8]

21. Acella did not file a New Drug Application ("NDA") with the FDA before it began manufacturing, marketing, and selling NP Thyroid.

---

[7] Exhibit 1, Acella's Amended Complaint in *Acella v. Westminster*, ¶ 2.
[8] Exhibit 6, Acella's description of "NP Thyroid® (THYROID TABLETS, USP)" (also available at: https://www.acellapharma.com/wp-content/uploads/2019/08/NP-Thyroid-flat-PI-7-22-19A-FPO.pdf) (last accessed May 10, 2020). A 60-milligram tablet contains one grain of thyroid.

22. Acella is aware—as Acella stated in a cease and desist letter it sent to a competitor—that selling a new drug that requires FDA approval without such approval "is in serious violation of the Federal Food, Drug, and Cosmetic Act (FFDCA) and related FDA regulations and compliance policies."[9] Indeed, Acella informed a competitor who had allegedly not received such approval that "there is not a legal basis for you or anyone in association with you to manufacture, distribute, or sell such Levothyroxine and Liothyronine products in the United States."[10] But Acella itself has persisted to this day in flouting the same rules.

The FDA's Prior Inspections of Acella's Manufacturing Practices

23. From March 19–22, 2012, the FDA conducted a Good Manufacturing Practices ("GMP") inspection of Acella. That inspection found, among other things, that "[t]he firm was marketing several unapproved drugs" and that "the quality unit responsibilities were not in writing."[11] The FDA further observed that "a system to facilitate recalls had not been

[9] Exhibit 7, October 6, 2017 Cease and Desist Letter from Acella to Westminster filed in *Acella v. Westminster*, dkt. 27-2.
[10] *Id.*
[11] Exhibit 4, EIR at 4.

established." But Acella showed no interest in addressing these issues: "Firm management refused a regulatory meeting with the Atlanta District Office."[12]

24. From August 26 through October 31, 2013, the FDA again inspected Acella and noted eight violations. These included findings that "the quality control unit lacked responsibility for approving or rejecting drug products manufactured, processed, packed and held under contract by another company; . . . cGMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them; . . . lack of process validation; . . . and root cause was not determined for several out- of- specification investigations."[13]

25. From October 20–28, 2015, the FDA again inspected Acella and noted three violations. As in prior inspections, the FDA noted that it was still the case that "the quality unit responsibilities were not in writing" and that "a system to facilitate recalls had not been established."[14]

[12] *Id.*
[13] *Id.*
[14] *Id.* at 4-5.

Acella's Dispute with its Competitor Westminster

26. Despite its own lack of compliance with FDA regulations and requirements, Acella took aggressive action in 2017 and 2018 to try to keep a competitor out of the thyroid market. During this dispute, Acella made assertions that show that it was fully aware of FDA requirements with which it failed to comply, that Acella knew that such conduct could give rise to investigations and enforcement action, and that Acella knew that such conduct could also give rise to concurrent civil liability.

27. On October 6, 2017, Acella sent a cease-and-desist letter to Westminster Pharmaceuticals, LLC, demanding that Westminster not bring a competing thyroid medication to market. In that letter, Acella—in addition to the statements quoted above (¶ 22, *supra*)—told Westminster that selling levothyroxine and liothyronine products in the United States without approval "risks serious enforcement actions and associated penalties and costs."[15] Acella detailed the potential multi-million dollar consequences of such an investigation and warned that "[s]uch FDA actions are becoming

[15] Exhibit 7, Acella's October 6, 2017 Cease and Desist Letter to Westminster October 6, 2017 Cease and Desist Letter from Acella to Westminster (emphasis in original).

more frequent as companies attempt to violate the directive."[16] Acella further warned that it was "investigating potential . . . claims which we believe will exist if you market and sell the product."

28. In its October 17, 2017 response to Acella's letter, Westminter observed that "perhaps what is most disconcerting, is that **Acella itself** has been selling its NP Thyroid product (aka Acella) since 2010 which contains levothyroxine and livothyronine [*sic*] as the active pharmaceutical ingredients; yet, we have been unable to locate the NDA that Acella filed for this product. (We assume that Acella must have filed an NDA for this product since you are now accusing Westminster of FDA violations for its failure to do so.) Please immediately send us your NDA number for Acella's NP Thyroid product."[17]

29. Acella did not—and could not—provide such a number to Westminster because it did not have one. After the FDA's 2019–2020 inspection of Acella, discussed further below, the "FDA . . . determined that [Acella] is distributing NP Thyroid, a biological product, without FDA

[16] *Id.*
[17] Exhibit 8, Response to Acella's Cease and Desist Letter filed in *Acella v. Westminster*, dkt. 27-3.

approval or a valid biologics license." In the *Westminster* dispute, the pot was calling the kettle black.

30. But that did not stop Acella from filing suit and making a variety of allegations that are directly relevant to its own misconduct in this case—particularly when it comes to the express representations that Acella makes to consumers by putting the phrase "Thyroid Tablets, USP" on its pill bottles.

31. In its Amended Complaint in the Westminster matter,[18] Acella made the following allegations, among others:

a. "If a drug ingredient or drug product has an applicable USP quality standard (in the form of a USP-NF monograph), it must conform in order to use the designation 'USP' or 'NF'. A monograph includes the name of the ingredient or preparation; the definition; packaging, storage, and labeling requirements; and the specification. The specification consists of a series of tests, procedures for the tests, and acceptance criteria. Drug products must have the specified strength, quality, and purity in order to comply with the requirements of the monograph and relevant general chapters." ¶ 22;

[18] Exhibit 1.

b. "Such labeling and advertising indicates to purchasers, distributors, and the general public that the Westminster USP Thyroid product complies with the applicable USP monograph." ¶ 26;

c. "Given [Defendant's] failures to satisfy USP requirements, the labeling on [its] USP Thyroid product as 'Thyroid Tablets, USP' and [its] representations that the product meets USP standards are objectively, demonstrably, and literally false and/or misleading." ¶ 29.

d. "[T]he false advertising of the Westminster USP Thyroid product has a material impact on purchasing decisions by both pharmacies and ***consumers***. In particular, given the well-accepted nature, acceptance and statutory force of the USP requirements, purchasers, such as pharmacies, would not purchase products for their inventory that are not compliant with applicable USP requirements." ¶ 32 (emphasis added).

e. Westminster's false and misleading statements and deception have and will have a material effect on purchasing decisions, such as by pharmacies and/or ***consumers***, who will incorrectly

believe that they are purchasing a product that is compliant with USP requirements." ¶ 39 (emphasis added).

f. "By such false statements, Westminster falsely represents that [its] USP Thyroid product has sponsorship, approval, characteristics, ingredients, uses, benefits, and/or quantities that it does not have." ¶ 49.

g. "[B]y such actions, Westminster represents that [its] USP Thyroid product is of a particular standard, quality, or grade or that goods are of a particular style or model, when they are in fact of another. Furthermore, such conduct creates a likelihood of confusion or of misunderstanding." ¶ 50.

32. Everything that Acella said about the factual and legal importance of the phrase "Thyroid Tablets, USP" in the *Westminster* matter is equally true of the phrase "Thyroid Tablets, USP" on Acella's own bottles of NP Thyroid medication.

Acella Expressly Markets its Commitment to Testing and Good Manufacturing Practices to Consumers

33. As set out above, Acella's inclusion of the phrase "USP" on its bottles is an express factual representation that Acella itself admits has a

"material impact" on the purchasing decisions of "consumers."[19] But that's not the only express representation that Acella makes to consumers about the quality, production methods, and content of NP Thyroid.

34. Acella made various safety and efficacy claims directly to patients, which Acella intended to influence patients and which constitute express warranties. For example, in marketing materials published in or around February 2019, Acella warranted as follows:

[19] Exhibit 1, Acella's Amended Complaint in *Acella v. Westminster*, ¶¶ 32, 39.

[20]

[20] Exhibit 9, Acella marketing material titled "NP Thyroid: A Natural Choice for Thyroid Therapy" with the identifier "Control Number 02/2019."

35. As shown above, among other claims, Acella warranted that it used "[b]atch-to-batch testing to ensure consistent T4 and T3," which is necessary to maintain consistent thyroid levels, and that NP Thyroid was "[m]ade with the highest quality standards under cGMP."

36. Likewise, an Acella advertisement published in or around September, 2019, includes promises of "[b]atch to batch testing to ensure consistent T4 & T3."[21] This advertisement also had a "conversion" chart comparing the different available doses of NP Thyroid to competitor products based on the amount of active ingredient.

37. Similarly, Acella marketing materials published in or around June 2021 claim that NP Thyroid is, among other things, "[b]atch-to-batch tested to ensure every dose delivers consistent T4 and T3," and "[m]ade with the highest quality standards under current Good Manufacturing Practice (cGMP) regulations."[22]

---

[21] Exhibit 10, marketing materials titled "A Natural* Choice for Thyroid Therapy," with the identifier "Rev. 0919" and the notation "Accessed August 8, 2019" on certain citations.

[22] Exhibit 11, marketing materials titled "NP Thyroid® May Help You Change Your Perspective," citing "Data on file. Acella Pharmaceuticals, LLC; June 2021" for certain claims.

38. Acella also claims on the front page of its NP Thyroid website that "[t]he makers of NP Thyroid implement quality measures above and beyond the FDA's guidance,"[23] while the truth is that Acella has deliberately disregarded FDA standards for years.

39. Acella made these and other marketing claims to induce patients to switch from other hypothyroidism medication to the supposedly "natural" and high-quality NP Thyroid. For example, Acella's website npthyroid.com contains a section entitled "For Patients," which describes the supposed superiority of NP Thyroid and encourages patients to contact their physicians about switching to Acella's drug—and, if necessary, to find a physician to prescribe NP Thyroid.[24]

40. Acella's representations were false, and Acella knew it. As explained below, during the same period Acella was making these claims to the public, the FDA was uncovering a variety of issues related to the inadequacy of Acella's manufacturing standards, quality control, and testing.

---

[23] Exhibit 12, Screenshot of the homepage of https://npthyroid.com (screenshot created May 11, 2022).

[24] *See* Exhibit 13, Screenshot of the "For Patients" section of Acella's NP Thyroid website, https://npthyroid.com/for-patients/ (screenshot created May 12, 2022).

The 2019–2020 FDA Inspection of Acella

41. Despite its patient-facing claims about the safety and quality of its manufacturing processes, Acella has experienced turmoil behind the scenes for years. As set out above, the FDA found multiple violations related to Acella's quality control going back to at least 2012. But being repeatedly chastised by the FDA did not make Acella clean up its act. Instead, the FDA's inspection in December 2019 through January 2020 found the same types of violations and resulted in a warning letter and three recalls—the third of which included NP Thyroid pills purchased by Plaintiff. Below, Plaintiff describes Acella's recent manufacturing issues, as found by the FDA; the conditions discussed below are those in place at Acella when it made many of the representations described in the prior section.

42. On December 17–20 and 23, 2019 and continuing on January 2–3 and 6–7, 2020, the FDA inspected Acella.

43. According to the FDA's Establishment Inspection Report, "[t]he inspection found the following deficiencies: (1) There is no quality control unit; (2) Complaint procedures are deficient in that they do not include provisions that allow for the review to determine if the complaints represent serious and unexpected adverse events which are required to be reported to

FDA; and (3) Written complaint records do not include, where known, reply to complainant."[25]

44. With respect to the observation "[t]here is no quality control unit," the FDA elaborated: "The documentation your firm uses for the release of NP Thyroid is not sufficient to make a determination about the quality of the drug product. Your firm approves and releases batch [*sic*] of bulk NP Thyroid drug products by merely reviewing the manufacturing batch record and the finished product Certificate of Analysis provided by your contract manufacturer, [redacted by the FDA]. The data of the final product testing is not verified to confirm the integrity and results of the Certificate of Analysis. Without any assurance of the quality through further testing, the product is eventually released to consumers."[26]

45. During this inspection, Acella's management admitted that "Acella has the ultimate authority to release their drug products, including NP Thyroid. Mr. [Allen] Fields[, Acella's Vice President of Clinical and Regulatory Affairs,] stated, 'We're responsible for all of it', referring to the product."[27]

---

[25] Exhibit 4, EIR at 2.
[26] *Id.* at 17.
[27] *Id.* at 18.

46. Despite being responsible for the drugs it produces, the FDA found that Acella "does not review any testing performed on the bulk tablets." Instead, a "Certificate of Analysis (COA)" that Acella receives from an associated manufacturer "is the only documentation of the final product testing of NP Thyroid bulk tablets that Acella management reviews before being released." But "the batch record does not include raw data and test performed."

47. Instead of testing batches or reviewing testing data, Acella representatives told FDA investigators "they trust" their manufacturing associate(s), and they performed occasional audits. But the FDA observed that, "[d]uring their audit, they are reviewing the final product testing pact of less than 1% . . . , and most of the batches manufactured of NP Thyroid would have been consumed or expired" by the time Acella performed its audit.[28]

48. After learning about Acella's quality control process—to the extent one existed—the FDA's investigator "explained to management that their review is not sufficient to release the NP Thyroid batches."[29]

[28] *Id.* at 19.
[29] *Id.* at 19.

49. To summarize, when the FDA performed this review, Acella touted "[b]atch-to-batch testing to ensure consistent T4 and T3" in marketing materials for NP Thyroid. But the FDA's inspection found that Acella not only fails to test batches itself, but it also "does not review any testing documentation before releasing the product for distribution."[30]

50. In addition to its quality control issues, the FDA cited Acella for two issues related to patient complaints that show that Acella adopted policies and practices designed to evade FDA review and ignore patients' safety concerns. These two complaint-related delinquencies cited by the FDA show that Acella adopted a two-front policy of silence when it came to complaints—(1) don't report them to the FDA and (2) don't respond to the patient.

51. *First*, Acella attempted to evade FDA scrutiny by classifying adverse reactions reported by patients as "nonserious"—even events that required hospitalization. Specifically, the FDA wrote that, during its "review of the adverse events reported to the firm, it was noted that most of the

[30] *Id.* at 19.

reported side effects were classified as 'nonserious and unexpected,' ***thereby precluding the firm from reporting these events to the FDA.***"[31]

52. The "adverse events" reported by patients to Acella, but not reported by Acella to the FDA, "included but were not limited to: heart palpitations; alopecia (loss of hair); altered menstrual cycle; depression; elevated blood pressure; and severely low Thyroid Stimulating Hormone (TSH) levels in cases where levels were close to within range pre-NP Thyroid medication therapy."[32]

53. Further, "in many of the complaints reviewed by [the FDA], the complainants deemed effects from their therapy serious enough to require a visit to the emergency room or primary care practice, the need to halt the self-administration of the medication, and/or reverting to an alternative therapy to halt the often-debilitating side effects."[33]

54. Despite the seriousness of many of the reported events, "roughly 98 percent (231 out of 235) of . . . NP Thyroid related complaints that were initially categorized as adverse events [from March 2019 through December 2019] were later reclassified as 'non-serious, unexpected' upon subsequent

[31] *Id.* at 11.
[32] *Id.* at 11.
[33] *Id.* at 11.

evaluation" and not reported to the FDA.[34] Acella and the company with which it worked regarding patient complaints "triaged and classified almost all complaints as 'non-serious and unexpected' without providing any reasonable rationale or documented evidence . . . for making these classifications."[35]

55. While Acella works with another company with respect to patient complaints, Acella "conceded" to the FDA "that final review and assessment of NP Thyroid product complaints rests with Acella."[36] Further, Acella's Vice President of Clinical and Regulatory Affairs, Mr. Allen Fields, described the company to which Acella "outsourced" the "role of triaging these complaints" as "an arm of Acella's quality control unit" to the FDA.[37]

56. *Second*, at the same time Acella down-graded complaints to avoid reporting serious adverse events to the FDA, Acella appears to have adopted a uniform policy of stonewalling complaining customers. Specifically, the FDA "noted that there was a recurring trend of management's lack of reply to

[34] *Id.* at 11.
[35] *Id.* at 12.
[36] *Id.* at 12.
[37] *Id.* at 23.

the complainants before, during and after an investigation, even when complainant explicitly requested a reply from the firm."[38]

57. The FDA's review found that, between March 2019 and October 2019, Acella "received, investigated, and closed approximately 414 complaints connected with varying dosage forms of the NP thyroid medication. Yet, firm management was unable to provide documented evidence of replying to complaints." Indeed, Acella's policies for handling complaints "lacked the requirement to reply to complainants in writing."[39]

58. The FDA "made firm management aware that reply to complainants was a quality control unit function and requirement in accordance with the Code of Federal Regulations."[40]

59. The picture that emerges from the FDA's 2019–2020 inspection report is one of a company that knows about its problems but doesn't care. Acella shipped out drugs without doing the bare minimum to test them—or even review testing data performed by its associates. And Acella knew that the drugs it was shipping out sight-unseen were often unsafe; it was getting hundreds of complaints over the course of just a few months—many of them

[38] *Id.* at 24.
[39] *Id.* at 24.
[40] *Id.* at 24.

about symptoms linked to sub- or super-potent thyroid medication. But instead of reporting these events to the FDA as required, Acella and its associates simply re-classified them to try to sweep them under the rug. And, as a policy, Acella gave patients who bought its drugs the cold shoulder—even when they reported that they ended up in the emergency room thanks to its drugs.

60. Acella's top management showed little interest in the FDA's inspection: "Harold (Art) Deas, Jr., Chief Executive Officer, was available for a brief period during the first day of inspection" but otherwise absented himself while FDA inspectors were in his company's offices for weeks.[41]

61. In later correspondence with the FDA, Acella represented that "all actions were completed as of February 28, 2020" to address the quality control issues raised by the agency.[42]

62. But that representation was false. Less than a week later, Acella distributed defective subpotent NP Thyroid that would eventually become part of its third recall—finally being pulled from the shelves more than a

[41] *Id.* at 8.
[42] Exhibit 14, Acella's March 31, 2020 Letter to the FDA.

year later. Nor was that the only serious quality control problem that came to light seemingly only because the FDA was scrutinizing Acella.

The FDA's Inspection of Acella's CMO, Allay Pharmaceuticals, LLC

63. During the FDA's inspection of Acella, Acella's management "stated that they trust their CMO with the final product testing result and that is the reason why they only rely on a COA to release batches."[43] The term "CMO" refers to a contract manufacturing organization—a company that works with drug-makers like Acella on a contract basis to help with various aspects of drug development and manufacturing.

64. Based on the investigation of counsel, Acella's CMO referenced by the passage above is Allay Pharmaceuticals, LLC ("Allay").

65. Acella and Allay worked in close coordination to make, market, and sell NP Thyroid, and they were jointly responsible for it in many respects. For instance, both Acella and Allay "are responsible for determining adequate drug specifications."[44] Further, Acella "developed" the "active ingredient assay specification . . . for levothyroxine and liothyronine in [its] NP Thyroid products" with Allay.[45] And Acella and Allay "are responsible for

[43] Exhibit 4, EIR at 21.
[44] Exhibit 3, Acella Warning Letter.
[45] *Id.*

all label claims for the product."[46] Indeed, the "FDA regards contractors as extensions of the manufacturer."[47]

66. After the many serious and potentially dangerous issues revealed by the FDA's 2019–2020 inspection of Acella, the FDA decided to inspect Allay—Acella's CMO involved in the production of NP Thyroid. The FDA conducted this inspection from May 5 to 15, 2020. As with the FDA's inspection of Acella, this inspection revealed a whole host of issues related to drug quality and would eventually result in an FDA Warning Letter.[48]

67. Specifically, the FDA found that Allay had engaged in "significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals." Further, the FDA found that drugs it produced were "adulterated" due both to these CGMP violations and, with respect to drugs believed to be NP Thyroid, due to their "failure to conform to compendial standards for strength, quality, or purity."

---

[46] *Id.*
[47] *Id.*
[48] Exhibit 15, January 27, 2021 FDA Warning Letter to Allay ("Allay Warning Letter") (also accessible at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/allay-pharmaceuticals-llc-609023-01272021) (last accessed May 9, 2022)

68. During its investigation of Allay, the FDA collected three samples of tablets believed to be NP Thyroid from Allay, and "[a]ll three samples were sub-potent for the active ingredient."

69. Among many other findings, the FDA concluded that Allay's "manufacturing failures indicate that you do not have an adequate ongoing program for monitoring process control to ensure stable manufacturing operations and consistent drug quality."

70. In addition to its manufacturing failures, the FDA found that the "active ingredient assay specifications [Allay] established with your product owner"—believed to be Acella—were "outside of the USP acceptance criteria" and therefore "adulterated."[49] "Articles represented as a drug recognized in an official compendia must conform to the compendial standards for strength, quality, or purity."

71. After purportedly revising its acceptance criteria, the FDA found that Allay then failed to perform "an investigation . . . to ensure that previously released lots met your revised assay specifications." Instead, "FDA investigators found 13 lots within expiry that exceeded your new assay

[49] *Id.*

specification during release or stability testing. These lots should have been identified in your investigation."

72. The 13 lots identified by the FDA—not Acella or Allay—are believed to be the 13 lots subject to Acella's first recall, discussed below.

Acella's First Recall

73. On May 21, 2020, Acella announced that it was "recalling a total of 13 lots of 30- mg, 60-mg and 90-mg NP Thyroid® (thyroid tablets, USP)" because testing found "the product may have up to 115.0% of the labeled amount of Liothyronine (T3)."[50]

74. The notice, which was also published by the FDA, also stated: Patients being treated for hypothyroidism (underactive thyroid), who receive superpotent NP Thyroid®, may experience signs and symptoms of hyperthyroidism (overactive thyroid) which include, but are not limited to, weight loss, heat intolerance, fatigue, muscle weakness, hypertension, chest pain, rapid heart rate, or heart rhythm disturbances. Pregnant women who take superpotent NP Thyroid® may also experience negative maternal and

[50] Exhibit 16, Acella's First Recall Announcement (also accessible at: https://www.acellapharma.com/news/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-of-certain-lots-of-np-thyroid-thyroid-tablets-usp-due-to-super-potency/) (last accessed May 9, 2022).

fetal outcomes including miscarriage and/or impairment to fetal development. Patients should talk to their healthcare professional before they stop taking their NP Thyroid® medicine."[51]

The FDA's Warning Letter to Acella

75. After exchanging correspondence with Acella following the 2019–2020 inspection, the FDA issued the Acella Warning Letter on August 14, 2020.

76. The FDA's "warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals."[52]

77. The FDA informed Acella that, with respect to NP Thyroid, "[b]ecause [Acella's] methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug product is adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act."[53]

---

[51] *Id.*
[52] Exhibit 3, Acella Warning Letter (citing Title 21 Code of Federal Regulations (CFR), parts 210 and 2011 (21 CFR parts 210 and 211)).
[53] *Id.* (citing 21 U.S.C. 351(a)(2)(B)).

78. The FDA further found that Acella's "NP Thyroid drug products are adulterated under section 501(b) of the FD&C Act, 21 U.S.C. 351(b), for failure to conform to compendial standards for strength, quality, or purity."

79. Elaborating on these findings, the FDA informed Acella that the agency's "investigators observed specific violations including, but not limited to," two issues related to quality control.

80. *First*, the FDA informed Acella: "Your firm failed to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity."[54]

81. With respect to this issue, the FDA focused on problems related to the active ingredients of NP Thyroid. Specifically, the FDA informed Acella that the "active ingredient assay specifications you established with your CMO for levothyroxine and liothyronine" was outside of the "assay acceptance criteria" of "the United States Pharmacopeia (USP) monograph

[54] *Id.* (citing 21 CFR 2111.160(b)).

for Thyroid Tablets, USP."[55] "Thyroid Tablets outside of the USP acceptance criteria are adulterated within the meaning of 501(b) of the FD&C Act, 21 U.S.C. 351(b), in that their strength, quality, or purity falls below the standards set forth in an official compendium recognized in the FD&C Act."[56]

82. In its warning letter, the FDA went on to disclose that it was an FDA investigation—and not Acella's own quality control processes—that led to Acella's first recall. Specifically, the "FDA inspected [Acella's] CMO from May 5 to 15, 2020, and found 13 lots within expiry . . . that exceeded 110.0% USP specification during release or stability testing. We acknowledge that your firm subsequently agreed to voluntarily recall these 13 lots. However, ***these lots should have been identified in your earlier investigation and communication***."[57]

83. *Second*, the FDA identified the following violation: "[Acella] failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers,

[55] *Id.*
[56] *Id.*
[57] *Id.* (emphasis added).

closures, in-process materials, packaging materials, labeling, and drug products."[58]

84. With respect to this violation, the FDA elaborated on a number of failures by Acella and its CMO related to "stability data," which "is critical for ensuring that products maintain their identity, strength, quality, purity, and safety throughout their labeled shelf-lives."[59]

85. The FDA further observed: "Per the quality agreement with your CMO, both you and your CMO are responsible for all label claims for the product. . . ."[60]

86. In addition to these violations, the FDA's warning letter includes the following under the heading "FDA Sample Results of Thyroid Tablets": "FDA sampled NP Thyroid (Thyroid Tablets, USP), 120mg strength lot M328J19-8 from your facility and found low, out- of-specification results for both active ingredients. Because 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

[58] *Id.* (citing 21 CFR 211.22(a)).
[59] *Id.*
[60] *Id.*

doses." As was customary, Acella failed to identify these critical deviations itself.

87. With respect to contract manufacturers, the FDA informed Acella: "Drugs must be manufactured in conformance with CGMP. FDA is aware that many drug manufacturers use independent contractors such as production facilities, testing laboratories, packagers, and labelers. FDA regards contractors as extensions of the manufacturer."

88. Finally, the FDA informed Acella: "Based on the information your firm submitted to FDA's electronic Drug Registration and Listing System and the information collected during the December 17, 2019–January 7, 2020 inspection, FDA has determined that your firm is distributing NP Thyroid, a biological product, without FDA approval or a valid biologics license." In other words, Acella was doing exactly what it told its competitor in *Westminster* was illegal and deceptive. Acella *still* refuses to obtain FDA approval to sell NP Thyroid.[61]

[61] Exhibit 17, FDA National Drug Code Directory results for NP Thyroid (demonstrating that, as of May 12, 2022, Acella has failed to apply for approval to sell NP Thyroid).

Acella's Second Recall

89. Despite the FDA's warning, Acella kept making and selling defective NP Thyroid pills. The company was forced to undertake a second recall, announced on September 17, 2020.

90. The recall announcement identified two lots of NP Thyroid and stated: "The products are being recalled because testing has found these lots to be sub potent. The product may have as low as 87% of the labeled amount of levothyroxine (T4)."[62]

91. The recall notice further stated: "Patients being treated for hypothyroidism (underactive thyroid), who receive sub potent NP Thyroid®, may experience signs and symptoms of hypothyroidism (underactive thyroid) which may include, fatigue, increased sensitivity to cold, constipation, dry skin, puffy face, hair loss, slow heart rate, depression, swelling of the thyroid gland and/or unexplained weight gain or difficulty losing weight. There is reasonable risk of serious injury in newborn infants or pregnant women with hypothyroidism including early miscarriage, fetal hyperthyroidism, and/or

[62] Exhibit 18, FDA Announcement of Acella's Second Recall (also accessible at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-two-lots-np-thyroidr-thyroid-tablets) (last accessed May 9, 2022).

impairments to fetal neural and skeletal development. In elderly patients and patients with underlying cardiac disease toxic cardiac manifestations of hyperthyroidism may occur, such as cardiac pain, palpitations or cardiac arrhythmia."

92. The two lots subject to this recall had expiration dates of October and November 2020. In other words, Acella did not identify that the NP Thyroid subject to the second recall was defective until 1–2 months before the pills were set to expire regardless. Meanwhile, members of the Class had been buying and taking those pills on the basis of Acella's false representations.

Acella's Third Recall

93. On April 30, 2021, the FDA published Acella's announcement of its third recall, which is its final recall to date. This third recall was for thirty-eight specific lots of subpotent thyroid medication. Plaintiff purchased NP Thyroid medication identified in the third recall.

94. The recall notice states: "The products are being recalled because routine testing has found these lots to be sub potent. The product contains

less than 90% of the labeled amount of liothyronine (T3) and/or levothyroxine (T4)."[63]

95. The third recall notice includes the same risk statement as the second recall notice and further states that "[t]o date, Acella has received 43 reports of serious adverse events that could possibly be related to this recall."[64]

96. Significantly, Acella's third recall includes lots produced over a huge timeframe—more than a year. The recall notice identifies "distribution dates" for the lots ranging from March 4, 2020 to March 19, 2021. Acella's deliberately weak quality control system failed to detect those issues for a year.

97. Throughout the period at issue, Acella persistently and knowingly sold NP Thyroid on the basis of representations that it knew were false.

---

[63] Exhibit 19, FDA Announcement of Acella's Third Recall (also accessible at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/acella-pharmaceuticals-llc-issues-voluntary-nationwide-recall-certain-lots-np-thyroidr-thyroid-0) (last accessed May 9, 2022).
[64] *Id.*

The September 2021 FDA Inspection of Acella

98. The FDA's website indicates that the agency completed another inspection of Acella ending September 17, 2021.[65]

99. According to the "Inspection Citation Details" section of the FDA's website, the FDA cited Acella for the following violations during this inspection:

a. "The quality control unit lacks the responsibility and authority to approve and reject all components, drug product containers, closures, in process materials, packaging material, labeling and drug products";

b. "Employees engaged in the manufacture, processing, packing and holding of a drug product lack the education and experience required to perform their assigned functions";

c. "Written production and process control procedures are not followed in the execution of production and process control functions";

[65] Exhibit 20, Screenshot of FDA's "Firm Profile" for Acella (also accessible at: https://datadashboard.fda.gov/ora/firmprofile.htm?FEIi=3006691461) (last accessed May 9, 2022).

d. "There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed"; and

e. "Procedures describing the handling of all written and oral complaints regarding a drug product are not followed."

100. In other words, it appears that the FDA's citations of and warning letter to Acella following the 2019–2020 inspection had no real effect on Acella's practices. According to the FDA's September, 2021, citations, Acella's quality control failures continue to be front-and-center, and it appears that Acella continued to "distribute[]" batches of drugs that "fail[] . . . to meet . . . [Acella's] specification" without even trying to figure out what caused the problems.

101. Based on Acella's repeated quality issues, it is likely that Acella sold additional defective NP Thyroid that was not recalled due to Acella's refusal to implement the quality-control measures to identify defective drugs before they are distributed to patients.

Class Allegations

102. Plaintiff seeks to represent the following class (the "Class"):

> All persons in the United States who purchased or paid for NP Thyroid that was subject to Acella's recalls or that was similarly defective but which Acella failed to recall.

103. Specifically excluded from the Class are Defendant, Defendant's officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendant, and any of its heirs, successors, assigns, or other persons or entities related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

104. Subject to additional information obtained through further investigation and discovery, the definition of the Class may be expanded or narrowed by amendment or amended complaint.

105. *Numerosity*. The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are tens to hundreds of thousands of members in the Class. Although the precise number of members of the Class is unknown to Plaintiff, the true number of members of the Class is known by Defendant and may be determined through discovery. Members of the Class may be

notified of the pendency of this action by mail and/or publication through the distribution records of Defendant and third-party retailers and vendors.

106. *Existence and predominance of common questions of law and fact.* Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

a. whether the NP Thyroid tablets manufactured, distributed, and sold by Defendant were in fact defective;

b. whether Defendant knew or should have known that the NP Thyroid tablets were in fact defective;

c. whether thyroid medication that does not contain the amount of active ingredient indicated on the bottle is worthless;

d. whether providers, pharmacists, and patients rely on the amount of active ingredient in thyroid medication when making prescribing and purchasing decisions;

e. whether the designation "Thyroid Tables, USP" on the pill bottles at issue was false;

f. whether Acella's claims of "batch-to-batch testing" of the pills at issue was false;

g. whether Acella's express claims related to cGMP compliance were false with respect to the pills at issue;

h. whether Acella committed fraud with respect to its statements and conduct at issue in this case;

i. whether Acella acted together as part of an enterprise for RICO purposes with the contract manufacturers and other entities involved in the production, marketing, and distribution of NP Thyroid; and

j. whether Plaintiff and the Class are entitled to damages, and the proper measure for such damages.

107. *Typicality*. Plaintiff's claims are typical of other members of the Class in that, among other things, all members of the Class were similarly situated and were comparably injured through Defendant's wrongful conduct. Further, there are no defenses available to Defendant that are unique to Plaintiff.

108. *Adequacy of Representation*. Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff has retained counsel that is

experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class.

109. *Superiority*. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The economic damages or other financial detriment suffered by individual members of the Class are relatively small compared to the burden and expense of individual litigation of their claims against Defendant. It would, thus, be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs committed against them. Furthermore, even if members of the Class could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

Causes of Action

Count 1: Fraud

110. Plaintiff realleges and incorporates paragraphs 1 to 109.

111. Acella knowingly made a variety of material false representations to consumers in order to sell NP Thyroid.

112. Acella made false representations on each and every bottle of NP Thyroid subject to this litigation. First, Acella expressly represented that each tablet in each bottle of NP Thyroid contained a specific amount of active ingredient. Second, Acella represented that its NP Thyroid tablets were "Thyroid Tablets, USP." These representations were false.

113. In addition to the false representations Acella printed on bottles of NP Thyroid, Acella made false representations in its marketing materials throughout the period at issue. Among these representations, Acella repeatedly touted its "[b]atch-to-batch testing to ensure consistent T4 & T3" and claimed that NP Thyroid is "[m]ade with the highest quality standards under cGMP." These representations were false.

114. Acella knew that the statements above were false when it made them. Instead of the "batch-to-batch testing" Acella promised, the FDA's investigation showed not only that Acella performed no testing whatsoever,

but also that Acella "does not" even "review any testing performed on the bulk tablets." Indeed, the FDA investigators observed that "[t]here is no quality control unit" at Acella.

115. With respect to cGMP compliance, Acella knew that it was not even following cGMP, much less operating with "the highest quality standards" under those practices. In fact, Acella had been cited by the FDA for quality issues going back to at least 2012. More directly, during the period at issue, the FDA found that Acella had committed "significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals."[66] Indeed, with respect to NP Thyroid, the FDA informed Acella that "[b]ecause your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug product is adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act."[67] Despite knowing that it was not true, Acella continued to advertise NP Thyroid's supposed cGMP compliance.

116. With respect to Acella's compliance with USP standards, Acella necessarily knew that, as found by the FDA, the "active ingredient assay

---

[66] Exhibit 3, Acella Warning Letter (citing Title 21 Code of Federal Regulations (CFR), parts 210 and 2011 (21 CFR parts 210 and 211)).
[67] *Id.* (citing 21 U.S.C. 351(a)(2)(B)).

specifications [Acella] established with [its] CMO for levothyroxine and liothyronine" was outside of the "assay acceptance criteria" of "the United States Pharmacopeia (USP) monograph for Thyroid Tablets, USP."[68] The FDA informed Acella that "Thyroid Tablets outside of the USP acceptance criteria are adulterated within the meaning of 501(b) of the FD&C Act, 21 U.S.C. 351(b), in that their strength, quality, or purity falls below the standards set forth in an official compendium recognized in the FD&C Act."[69]

117. Acella's knowledge regarding the meaning and materiality of the phrase "Thyroid Tables, USP" is further shown by its allegations against its competitor in the *Acella v. Westminster* matter. There, Acella alleged: "If a drug ingredient or drug product has an applicable USP quality standard (in the form of a USP-NF monograph), it must conform in order to use the designation "USP" or "NF". A monograph includes the name of the ingredient or preparation; the definition; packaging, storage, and labeling requirements; and the specification. The specification consists of a series of tests, procedures for the tests, and acceptance criteria. Drug products must have the specified

[68] *Id.*
[69] *Id.*

strength, quality, and purity in order to comply with the requirements of the monograph and relevant general chapters."[70]

118. As also alleged by Acella, including the phrase "Thyroid Tablets, USP" on labelling and advertising "indicates to purchasers, distributors, and the general public that [a producer's] USP Thyroid product complies with the applicable USP monograph."[71]

119. With respect to Acella's express representations regarding the amount of active ingredient in the pills at issue, Acella either knew that the NP Thyroid tablets it produced were sub- or super-potent or was recklessly indifferent as to whether the tablets contained the correct amount of active ingredient. As set out in the FDA's reports, Acella did not have the proper specifications in place for the active ingredients of NP Thyroid on the front end, then it did absolutely no testing whatsoever on the back end before its drugs went out to the public. If Acella did not know that many lots of NP Thyroid were sub- or super-potent before it sold them to the public, that was only because it was willfully blind and in complete dereliction of its duties with respect to drug manufacturing, testing, and quality control. Further, the

[70] *Acella v. Westminster*, dkt. 44, ¶ 22.
[71] *Id.* at ¶ 26.

fact that the third recall included lots with distribution dates that ranged for more than a year shows that Acella had the ability to test NP Thyroid all along, but it chose not to do so until it was too late.

120. Acella made each of the representations above in order to sell NP Thyroid. Indeed, Acella itself previously alleged that the phrase "Thyroid Tablets, USP," "has a material impact on purchasing decisions by both pharmacies and consumers. In particular, given the well-accepted nature, acceptance and statutory force of the USP requirements, purchasers, such as pharmacies, would not purchase products for their inventory that are not compliant with applicable USP requirements."[72] Acella's other false statements set out above likewise are designed to sell NP Thyroid by falsely touting batch-to-batch testing, cGMP compliance, and the consistent delivery of a specific amount of active ingredient.

121. Plaintiff and members of the Class were justified in relying on Acella's representations, as Acella intended. With respect to Acella's representations regarding the amount of active ingredient in each NP Thyroid tablet, Plaintiff and each and every member of the Class *necessarily* relied on the accuracy of Acella's representations. Because NP Thyroid is a

[72] *Acella v. Westminster*, dkt. 44 at ¶ 32.

prescription medication, it is prescribed in specific doses based on the amount of active ingredient. When a patient fills the prescription at the pharmacy or through the mail, they do so by asking for a specific dose based on the specific amount of active ingredient that is supposed to be in each tablet. Each and every person involved in the process—from doctors to pharmacists to patients—depends on manufacturers like Acella to deliver accurate information about what is in the drugs they sell, and this reliance is justified. The functioning of the health system depends on it.

122. The same is true of the phrase "Thyroid Tablets, USP" printed on each NP Thyroid bottle. As Acella itself alleged when it was suing its competitor, "given the well-accepted nature, acceptance and statutory force of the USP requirements, purchasers, such as pharmacies, would not purchase products for their inventory that are not compliant with applicable USP requirements."[73] As with the amount of active ingredient, it was justified for purchasers, including consumers, to rely on the accuracy of express, factual representations that Acella was making on its bottles of NP Thyroid tablets.

123. Plaintiff and each member of the Class were damaged by Acella's fraud.

[73] Exhibit 1, Acella's Amended Complaint in *Acella v. Westminster*, ¶ 32.

124. Georgia law governs the fraud claims of Plaintiff and members of the Class regardless of where each person purchased NP Thyroid. As recently articulated by the Supreme Court of Georgia, "at least with respect to a state where the common law is in force, a Georgia court will apply the common law as expounded by the courts of Georgia." *Coon v. Med. Ctr., Inc.*, 797 S.E.2d 828, 834 (Ga. 2017).

125. To the extent that there is any other state in the United States in which the common law is not in force, the law of fraud in such a state or states is consistent with Georgia law such that there is no conflict, and the Court can therefore apply Georgia law. *See*, *e.g.*, *Blockbuster Inv'rs LP v. Cox Enters.*, 724 S.E.2d 813, 815 (Ga. Ct. App. 2012) ("'If the laws of the states at issue do not conflict, there is no need to resolve the choice of law question, and the law of the forum applies.'") (alterations and citation omitted); *see also Fioretti v. Mass. Gen. Life Ins. Co.*, 53 F.3d 1228, 1234 n.21 (11th Cir. 1995) (noting that, when "there is no difference in the substantive law of the competing states," then "the court could simply apply the law of the forum state," which "enjoys the additional virtues of being more streamlined and less time-consuming" than alternative approaches).

126. On behalf of herself and the Class, Plaintiff seeks to recover the full purchase price of all defective NP Thyroid medication sold in the United States.

127. With respect to their economic injuries, the defective NP Thyroid tablets purchased by Plaintiff and each member of the class were worthless. Thyroid medication, including NP Thyroid, is a prescription drug. When doctors prescribe NP Thyroid to patients, they do so in specific dosages based directly on the amount of active ingredient that is supposed to be in the tablets. Patients need to take thyroid medication in the specific doses prescribed by their providers—not in some other dose. Purchasing thyroid medication that does not have the amount of active ingredient that it is supposed to have, like the NP Thyroid lots at issue in this case, is worthless in that it does not meet the intended purpose of treating a patient's specific medical condition with a specific dose of thyroid medication. In fact, Acella's defective NP Thyroid was worse than worthless—it was actively harmful—because patients who took it believed that they were properly treating their conditions and did not acquire medication with the correct amount of active ingredient when they needed to take it.

128. The FDA's warning letter drives home the importance of accurate dosing and the harm that can be caused by either sub- or super-potent thyroid medication: "Because of the narrow therapeutic range of [NP Thyroid], content uniformity is critical and it is especially important to prevent patients with hypothyroidism from receiving insufficient or excessive doses."[74]

129. Because the NP Thyroid pills Plaintiff and each member of the Class purchased were worthless (or worse), Plaintiff and the Class seek to recover the full purchase price of all defective NP Thyroid they bought.

130. This measure of damages is well recognized in defective drug cases involving a defendant's misrepresentation of the amount of active ingredient in a product. Addressing the same fundamental theory of recovery as applied to Acella's competitor, Westminster—which also manufactured thyroid medication with amounts of active ingredient that did not match those listed on the bottle—a sister court within the Eleventh Circuit reasoned:

> Plaintiffs' theory of injury rests on the plausible, common-sense allegation that they would not have purchased the thyroid tablets had they known the dosages listed on the labels did not reflect the actual dosages. Significantly, Plaintiffs' doctors prescribed them

[74] Exhibit 3, Acella Warning Letter.

> specific dosages of thyroid medication . . . . Taking the wrong amount of medication could have harmed Plaintiffs because, as the FDA explained, 'over or under treatment of hypothyroidism could result in permanent or life-threatening adverse health consequences.' These potential consequences support Plaintiffs' assertion that the dosages listed on the label were 'part of the basis of the bargain' they struck in buying the thyroid tablets. Accordingly, Plaintiffs suffered a concrete monetary injury when they paid for thyroid medication that they plausibly allege they would not have purchased had they known it did not contain the amount of [active ingredient] they thought they were receiving.

Yachera v. Westminster Pharm., LLC, 477 F. Supp. 3d 1251, 1263-64 (M.D. Fla. 2020). The same reasoning applies here.

131. On behalf of herself only, Plaintiff also seeks to recover for the personal injuries that she suffered because of Acella's fraud.

Count 2: Federal RICO (18 U.S.C. § 1964(c))

132. Plaintiff realleges and incorporates paragraphs 1 to 131.

133. While Acella is the lone defendant in this case at this time, it did not act alone. Instead, the FDA's Establishment Inspection Report shows that Acella brought NP Thyroid to market through a web of associated manufacturers and other companies, including Acella's CMO, Allay Pharmaceuticals, LLC.[75] In general, these companies are redacted in documents received from the FDA through open records requests. Plaintiff

[75] Exhibit 4, EIR at 5-7.

will be able to provide additional information regarding the identity of the companies involved in the allegations below after receiving discovery in this case.

134. These associated companies, including Allay, knew that Acella was engaged in fraud in connection with the sale of NP Thyroid and participated in that conduct.

135. Specifically, Acella operated and managed a RICO enterprise consisting of at least, to the extent these are each different entities: (1) itself, (2) the CMO that Acella informed the FDA they "trust" to do testing,[76] (3) the company involved in triaging complaints that Acella described to the FDA as "an arm of Acella's quality control unit,"[77] and (4) the CMO referenced by the FDA in its Acella Warning Letter by the phrase "both you and your CMO are responsible for all label claims for the product."[78] On information and belief, Allay is the CMO referenced in (4) above, probably also (2), and possibly also (3). Based on their corporate filings and information in the FDA inspection documents, Allay and Acella do not have common ownership or control. But

[76] *Id.* at 19.
[77] *Id.* at 23.
[78] Exhibit 3, Acella Warning Letter.

as a matter of contract and law they are jointly responsible for the production and labelling of NP Thyroid.

136. Through this enterprise, Acella and its associates, including Allay, engaged in a pattern of fraud to sell NP Thyroid based on qualities and characteristics that it did not actually have, as alleged in the prior Count. Acella and its associates accomplished this pattern of fraud through use of the mail and wires, in violation of 18 U.S.C. §§ 1341, 1343. This conduct gives rise to a civil RICO claim under 18 U.S.C. § 1964(c).

137. Acella's RICO violations damaged the property of Plaintiff and members of the Class because they were induced by Acella's fraudulent enterprise to spend money on NP Thyroid medication that was, in fact, worthless.

138. On behalf of herself and the class, Plaintiff seeks to recover the full purchase price of all defective NP Thyroid Acella sold in the United States. Plaintiff and the Class further seek treble damages and attorneys' fees.

Count 3: Statutory Strict Liability Under O.C.G.A. § 51-1-11

139. Plaintiff realleges and incorporates paragraphs 1 to 138.

140. As a Georgia manufacturer, Acella is subject to Georgia's strict liability statute, O.C.G.A. § 51-1-11.

141. Under O.C.G.A. § 51-1-11(a)(1), "[t]he manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained."

142. Plaintiff is a "natural person" as defined in this statute, as is each member of the Class. Under Georgia law, the phrase "natural person" is a defined term in the Georgia Code that includes all human beings regardless of whether they are citizens of Georgia. O.C.G.A. § 1-2-1(b). By statute, the phrase "natural person" in legislation specifically includes all three of "(1) Citizens [of Georgia]; (2) Citizens of the United States but not of [Georgia]; and (3) Aliens." O.C.G.A. § 1-2-2.

143. Acella is the manufacturer of NP Thyroid.

144. NP Thyroid medication is personal property.

145. NP Thyroid was sold to Plaintiff and each member of the class as new property.

146. Each of these sales was made directly by Acella, through a dealer, or through any other person.

147. Plaintiff and each member of the Class used or consumed Acella's NP Thyroid medication.

148. Plaintiff and each member of the Class suffered injury to their persons or property because NP Thyroid, when sold by Acella, was not merchantable and reasonably suited to the use intended. Specifically, because the NP Thyroid lots subject to Acella's recalls did not have the amount of active ingredient reflected on the bottle, it was not reasonably suited to the intended use of treating hypothyroidism and related disorders. As explained in the prior Count, the NP Thyroid purchased by Plaintiff and members of the Class was worthless, and they would not have bought it had they known it was defective.

149. The condition of the defective NP Thyroid tablets when sold to Plaintiff and each member of the Class is the proximate cause of their injuries.

150. On behalf of herself and the Class, Plaintiff seeks to recover the full purchase price of all defective NP Thyroid sold in the United States.

151. While Plaintiff does not seek to recover damages for personal injuries on a Class-wide basis, every member of the Class suffered a personal injury to some extent. Patients are prescribed thyroid medication, including NP Thyroid, in specific doses, and patients need to receive the right amount of medication in order to treat their particular conditions. When patients took NP Thyroid, they were ingesting hormones that necessarily had a physical effect in their bodies. Where the amount of active ingredient was different from the amount shown on the bottles of NP Thyroid, patients received either too much or too little thyroid medication to treat their conditions. As a matter of biology, this had an effect in each patient's body, and Acella's sub- and super-potent NP Thyroid necessarily but secretly caused patients to deviate from their prescribed treatment plans. While the physical effects of this deviation varied significantly from person to person—and Plaintiff does not

seek to represent a personal injury class as a result—every member of the Class suffered *some* physical injury from ingesting Acella's adulterated drugs.

152. Acella was manifestly aware that information it provided—including specific amounts of active ingredients and the phrase "Thyroid Tablets, USP" on bottles of NP Thyroid—would be used to make prescribing and purchasing decisions, and Acella intended for the information it provided to be used for those purposes. Indeed, Acella itself alleged in *Acella v. Westminster* that falsely labeling thyroid tablets "USP" when they are not USP-compliant "has a material impact on purchasing decisions by both pharmacies and consumers. In particular, given the well-accepted nature, acceptance and statutory force of the USP requirements, purchasers, such as pharmacies, would not purchase products for their inventory that are not compliant with applicable USP requirements." Dkt. 44, ¶ 32.

153. Plaintiff and each member of the Class are part of a foreseeable class of persons who Acella intended to rely on the false information it published, including the specific amounts of active ingredient and the phrase "Thyroid Tablets, USP" on the pill bottles at issue.

154. Acella is liable under O.C.G.A. § 51-1-11 regardless of the state in which members of the Class purchased NP Thyroid. Where members of the

Class purchased NP Thyroid in states that, like Georgia, recognize claims for strict liability against the manufacturer of prescription drugs, then there is no conflict, and the Court can apply Georgia law as the law of the forum state. *See*, *e.g.*, *Blockbuster Inv'rs LP v. Cox Enters.*, 724 S.E.2d 813, 815 (Ga. Ct. App. 2012) ("'If the laws of the states at issue do not conflict, there is no need to resolve the choice of law question, and the law of the forum applies.'") (alterations and citation omitted); *see also Fioretti v. Mass. Gen. Life Ins. Co.*, 53 F.3d 1228, 1234 n.21 (11th Cir. 1995) (noting that, when "there is no difference in the substantive law of the competing states," then "the court could simply apply the law of the forum state," which "enjoys the additional virtues of being more streamlined and less time-consuming" than alternative approaches).

155. Where members of the Class purchased NP Thyroid in states that do not recognize claims for strict liability under these circumstances, Acella is nevertheless subject to strict liability claims under O.C.G.A. § 51-1-11 as a matter of Georgia public policy. Specifically, the Supreme Court of Georgia has held that the law of states that do not recognize strict liability claims "and Georgia law are radically dissimilar in terms of the burden placed on persons seeking recompense for injuries caused by defective products."

Alexander v. GMC, 478 S.E.2d 123, 124 (Ga. 1996). Because applying the law of a state that does not recognize strict liability claims would leave a plaintiff "in exactly the position from which O.C.G.A. § 51-1-11 was intended to protect those who are injured by defective products placed in the stream of commerce in this state, . . . it is contrary to the public policy of this state as expressed in that statute." *Id.* Consequently, such a plaintiff "is entitled to have Georgia law applied to his [or her] claims." *Id.*

156. Acella is headquartered in Georgia. It is a citizen of the state and subject to the general personal jurisdiction of its courts. Acella's conduct, by and large, took place in Georgia. Its decisions to manufacture defective and adulterated thyroid medication and to sell that medication based on false express representations took place in Georgia. And Plaintiff and members of the Class were injured by defective products that Acella placed in the stream of commerce in this state. Acella had every expectation that, as a Georgia manufacturer, it would be liable under Georgia's strict liability law regulating the conduct of Georgia manufacturers. And it is.

157. In addition to Class-wide economic damages as set out above, Plaintiff seeks to recover for her personal injuries under O.C.G.A. § 51-1-11 on an individual basis only.

Court 4: Negligence

158. Plaintiff realleges and incorporates paragraphs 1 to 157.

159. Acella had a duty to exercise at least ordinary care to adopt manufacturing practices and procedures designed to avoid producing defective drugs.

160. Acella failed to observe the degree of care, precaution, and vigilance which the manufacture of dangerous prescription medication justly requires.

161. Specifically, Acella failed to adhere to cGMP standards required by law, failed to meet the manufacturing requirements required by law for labeling its drugs "USP," and otherwise failed to adhere to required testing and quality control standards as set out in the FDA's Establishment Inspection Report, Warning Letter, and related documents.

162. Plaintiff and the Class do not seek to impose any duty of care higher or different than federal laws and regulations governing Acella's production process. Rather, Plaintiffs and the Class allege that Acella's deviation from those standards, as documented by the FDA, was at the very least the result of negligence—if not intentional misconduct as alleged in certain prior Counts.

163. As the result of Acella's negligence (or worse), there were defects in the lots of NP Thyroid at issue when they left the manufacturer. Specifically, the NP Thyroid at issue was defective because the amount of active ingredient in each tablet deviated significantly from the amount listed on the bottle.

164. Plaintiff and the Class were injured by Acella's negligence (or worse) as described in prior Counts.

165. On behalf of herself and the Class, Plaintiff seeks to recover the full purchase price of all defective NP Thyroid sold in the United States.

166. On behalf of herself only, Plaintiff seeks to recover for the personal injuries she suffered as a result of ingesting Acella's defective NP Thyroid.

Count 5: Breach of Express Warranty Under O.C.G.A. § 11-2-313

167. Plaintiff realleges and incorporates paragraphs 1 to 166.

168. As alleged above, Acella made various express warranties directed to patients like Ms. Faulkner.

169. These express warranties include: (1) Acella's representation on each bottle of NP Thyroid that each tablet contains a specific amount of active ingredient, (2) Acella's representation on each bottle of NP Thyroid

that the product contains "Thyroid Tablets, USP," (3) Acella's repeated and consistent representations regarding "[b]atch-to-batch testing to ensure consistent T4 & T3" in marketing materials for NP Thyroid, and (4) Acella's repeated and consistent representations that the production of NP Thyroid meets or exceeds cGMP standards.

170. Acella's labelling and marketing claims are warranties because they are representations of fact Acella directed to patients which relate to NP Thyroid and which Acella intended to be part of the basis of the bargain—a reason for choosing NP Thyroid over other medications. *See, e.g.*, *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1324 (M.D. Ga. 2011) (applying Georgia warranty law to a drugmaker's marketing claims).

171. Acella breached each of the express warranties above. Contrary to its representations, Acella did not comply with cGMP standards, it did not perform batch-to-batch testing of NP Thyroid, it did not ensure consistent levels of T4 & T3, it did not meet the requirements to use the "USP" designation on its thyroid tablets, and the amounts of active ingredient in the tablets of NP Thyroid at issue were not the amounts reflected on the bottles.

172. Because Acella made the express warranties above directly to consumers, there is privity of contract between Acella on one hand and Plaintiff and members of the Class on the other as a matter of Georgia law.

173. Ms. Faulkner gave Acella notice of its breach of warranty in or about June 2021 when she spoke with Acella personnel on the company's "recall line." According to Ms. Faulkner's notes, she spoke with a nurse named Brittney Garwick and another Acella employee named Jenny.

174. In addition, this complaint serves as notice to Acella. *See Wal-Mart Stores, Inc. v. Wheeler*, 262 Ga. App. 607, 608–09 (2003). In light of the multiple recalls related to NP Thyroid, Acella is fully aware that it has been selling defective NP Thyroid medication and may face related claims. Consequently, Acella has not been prejudiced by any delay in notice regarding the warranty claims of Plaintiff and members of the Class.

175. Acella's breaches of its express warranties injured Plaintiff and members of the Class physically and economically.

176. Plaintiff and members of the Class can bring a claim under O.C.G.A. § 11-2-313 regardless of where they purchased NP Thyroid. Under O.C.G.A. § 11-1-301, Georgia's UCC "applies to transactions bearing an appropriate relation to this state." Here, Acella is a Georgia citizen, and most

of Acella's conduct, statements, and decisions that gave rise to Plaintiff's and the Class's claims took place in Georgia.

177. Applying Georgia warranty law to all purchases of NP Thyroid also advances the "core purposes of the U.C.C. [] to 'simplify, clarify, and modernize the law governing commercial transactions' and 'to make uniform the law among the various jurisdictions.'" *Erler v. Hasbro, Inc.*, 506 F. Supp. 3d 1275, 1284 (N.D. Ga. 2020) (Totenberg, J.). "To apply a host of different states' law to Plaintiff[']s[] putative class action contract claims under current circumstances would contravene those core purposes." *Id.* (applying Rhode Island law where it was the principal place of business of the defendant and "the common factor with respect to the twenty-eight Plaintiffs").

178. On behalf of herself and the Class, Plaintiff seeks to recover the full purchase price of all defective NP Thyroid that Acella sold in the United States.

179. On behalf of herself only, Plaintiff seeks to recover for the personal injuries she suffered as a result of ingesting Acella's defective NP Thyroid.

Count 6: Breach of Implied Warranties

180. Plaintiff realleges and incorporates paragraphs 1 to 179.

181. Georgia law recognizes two types of implied warranties. First, under O.C.G.A. § 11-2-314, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Second, under O.C.G.A. § 11-2-315, "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Acella breached both of these implied warranties.

182. Acella breached the warranty of merchantability for reasons including (1) the NP Thyroid tablets at issue were not "fit for the ordinary purposes for which such goods are used," O.C.G.A. § 11-2-314(2)(c), (2) they were not adequately "labeled," *id.* at (2)(e), and (3) they did not "[c]onform to the promises or affirmations of fact made on the container or label," *id.* at (2)(f).

183. Acella also breached the implied warranty of fitness for a particular purpose. Acella knew that Plaintiff and each member of the Class intended to use NP Thyroid to treat hypothyroidism and related conditions. Acella further knew that, to be fit for this purpose, the NP Thyroid tablets it

sold had to accurately reflect the amount of active ingredient in each tablet. Because the amounts of active ingredients in the NP Thyroid tablets at issue were different than the amount reflected by the bottles, the NP Thyroid tablets at issue were not fit for the particular purpose for which they were intended.

184. Regardless of whether Plaintiff or members of the Class purchased directly from Acella, the company's express warranties "bridg[ed] the gap" to patients so as to create privity under Georgia law. *Studebaker Corp. v. Nail*, 82 Ga. App. 779, 784 (1950); *accord Lee v. Mylan, Inc.*, 806 F. Supp. 2d 1320, 1325–26 (M.D. Ga. 2011) (holding that, "under Georgia law, privity of contract between the manufacturer and ultimate consumer is established when the manufacturer extends an express warranty to the ultimate consumer"). And "[o]nce privity is established, a plaintiff may bring claims for breach of the implied warranties of merchantability and fitness for a particular purpose."

185. Plaintiff provided and Plaintiff and the Class provide notice to Acella as described in the prior Count.

186. As described in the prior Count, Plaintiff and members of the Class can bring claims under Georgia's UCC regardless of where they purchased NP Thyroid.

187. Acella's breaches of its implied warranties injured Plaintiff and members of the Class physically and economically.

188. On behalf of herself and the Class, Plaintiff seeks to recover the full purchase price of all defective NP Thyroid that Acella sold in the United States.

189. On behalf of herself only, Plaintiff seeks to recover for the personal injuries she suffered as a result of ingesting Acella's defective NP Thyroid.

Count 7: Attorneys' Fees Under O.C.G.A. § 13-6-11

190. Plaintiff realleges and incorporates paragraphs 1 to 189.

191. Under O.C.G.A. § 13-6-11, a plaintiff can recover reasonable attorneys' fees incurred in the successful prosecution of a claim if the defendant has acted in bad faith with respect to the underlying situation or if the defendant is stubbornly litigious or causes the plaintiff unnecessary trouble and expense in the litigation.

192. Acella has acted in bad faith in connection with the production, marketing, and sale of defective NP Thyroid. Plaintiff and members of the Class therefore seek to recover attorneys' fees under O.C.G.A. § 13-6-11.

193. If Acella is stubbornly litigious or causes unnecessary trouble and expense, Plaintiff and the Class intend to seek fees on that basis as well.

Count 8: Punitive Damages

194. Plaintiff realleges and incorporates paragraphs 1 to 193.

195. Through its conduct alleged above, Acella showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences, entitling Plaintiff and the Class to punitive damages under O.C.G.A. § 51-12.5.1(b).

196. Because Acella's liability in this matter "arises from product liability, there shall be no limitation regarding the amount which may be awarded as punitive damages" against Acella. O.C.G.A. § 51-12-5.1(e).

197. Plaintiff and the Class seek uncapped punitive damages in an amount to be determined in the enlightened conscious of the jury, but in an amount no less than three times any compensatory damage award.

Prayer for Relief

Plaintiff and the Class respectfully request the following relief:

a. Trial by jury;

b. Compensatory and punitive damages in an amount to be determined at trial;

c. Treble damages under RICO;

d. Costs and attorneys' fees;

e. Pre- and post-judgment interest; and

f. All other appropriate relief.

Respectfully submitted this 12th day of May, 2022.

THE BLOCK FIRM LLC

/s/Max Marks
Aaron K. Block
Georgia Bar No. 508192
Max Marks
Georgia Bar No. 477397
Allison Bailey
Georgia Bar No. 478434
The Block Firm LLC
309 East Paces Ferry Road, Suite 400
404-997-8419
aaron@blockfirmllc.com
max.marks@blockfirmllc.com
allison.bailey@blockfirmllc.com

Counsel for Plaintiffs

CERTIFICATE OF TYPE STYLE AND SIZE

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

/s/Max Marks
Max Marks

ClassAction.org