EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
MACON DIVISION

PATRICIA FAYE ALLEN, Individually and as the Administrator of the Estate of Tracy Faye Edge, *Plaintiff,* **v.** **VINTAGE PHARMACEUTICALS LLC d/b/a PAR PHARMACEUTICAL; ENDO HEALTH SOLUTIONS, INC.; and RHODES PHARMACEUTICALS LP,** *Defendants.*	**CIVIL ACTION NO. 5:18-cv-00329-TES**

ORDER GRANTING MOTIONS TO DISMISS AND DENYING MOTION TO AMEND

There are five motions presently pending in this case: Defendants' Motions to Dismiss [Docs. 4, 13]; Defendant Rhodes Pharmaceuticals' ("Rhodes") Motion Seeking Judicial Notice [Doc. 5]; Rhodes's Motion to Strike Plaintiff's Amended Complaint [Doc. 17]; and Plaintiff's Motion to Amend her Complaint [Doc. 19]. As discussed below, Rhodes's Motion to Dismiss, Motion Seeking Judicial Notice, and Motion to Strike are **GRANTED**; Defendant Vintage Pharmaceuticals, LLC d/b/a Par Pharmaceutical's ("Par") Motion to Dismiss is **GRANTED**; and Plaintiff's Motion to Amend is **DENIED as futile**.

FACTUAL BACKGROUND[1]

On April 20, 2016, Plaintiff's daughter, Tracy Faye Edge, died from "Morphine and Amitriptyline toxicity" and "opioid toxicity" after being prescribed the two medications less than one month apart. [Doc. 19-1, ¶¶ 4, 8–10, 41, 56]. According to Plaintiff, Rhodes, who manufactured the morphine prescribed to Ms. Edge, and Par, who was a manufacturer of amitriptyline, knew or should have known of the danger posed by combining the two drugs but "failed to exercise ordinary care" and "issued no warnings regarding the toxicity." [*Id.* at ¶¶ 2, 5, 21–23]. Plaintiff also alleges that both Defendants "knew or should have known . . . that Plaintiff should have never been prescribed, dispensed, marketed or sold the prescription drugs that caused Plaintiff's death." [*Id.* at ¶ 33]. Moreover, Plaintiff claims that "opioid manufacturers such as Rhodes and [Par] market and claim in literature that opioids are safer than a Tylenol" and "encourage doctors to write prescriptions for opioids . . . [by] touting [them] as safe, and non-habit forming," even though such marketing is "false, misleading and causes harm," including the harm that befell Ms. Edge. [*Id.* at ¶¶ 59–62]. According to Plaintiff, Defendants had a duty to market "dangerous drugs" (presumably including morphine and amitriptyline) as "dangerous drugs of last resort." [*Id.* at ¶ 67]. In addition to marketing to doctors, Plaintiff claims that Defendants deliberately marketed to Ms. Edge by mail. [*Id.* at ¶ 17].

[1] The following facts are taken from Plaintiff's amended complaint and proposed amended complaint, which are identical.

With regard to Rhodes in particular, Plaintiff claims it knew or should have known "of the danger of opioid toxicity" and "that any opioid drugs prescribed to any patient . . . could prove fatal" but "continued to market and encourage doctors to prescribe opioids such as [m]orphine" anyway. [*Id.* at ¶¶ 24, 25]. Plaintiff also charges Par with failing to warn Ms. Edge[2] of the adverse effects associated with combining morphine and amitriptyline, even though it had a duty to issue such a warning under the Omnibus Budget Reconciliation Act of 1990. [*Id.* at ¶¶ 26, 27]. Plaintiff conclusorily and repeatedly alleges that these acts and omissions were the proximate cause of Ms. Edge's death and Plaintiff's injuries. [*Id.* at ¶¶ 35, 36, 40–42, 44, 47–49, 62, 64, 71].

PROCEDURAL HISTORY

Plaintiff filed her original complaint on September 10, 2018. [Doc. 1]. Rhodes filed its motion to dismiss on November 9, 2018 [Doc. 4], and Par filed its motion to dismiss on November 30, 2018 [Doc. 13]. On December 3, 2018—24 days after Rhodes filed its motion to dismiss and three days after Par filed its motion to dismiss—Plaintiff filed an amended complaint [Doc. 16], which Rhodes moves to strike as untimely [Doc. 17]. Fourteen days later (and likely in response to Rhodes's motion to strike), Plaintiff moved

[2] The amended complaint actually claims that Par should have warned "Plaintiff about the adverse effects associated with the Plaintiff's prescribed [m]orphine . . . combined with [a]mitriptyline . . . ." [Doc. 19-1, ¶ 26]. Because Patricia Faye Allen is a plaintiff to this action in her individual capacity as it relates to her wrongful death claim and there are no allegations that she took the drugs in question, the Court assumes Plaintiff intended to claim that Par failed to warn Ms. Edge of the adverse effects of mixing her prescriptions.

to amend her complaint and attached a proposed amended complaint identical to her previously-filed amended complaint. [Doc. 19].

As discussed herein, Rhodes' motion to strike is granted, as is its motion to dismiss. Par's motion to dismiss is likewise granted. Plaintiff's motion to amend is denied as futile.

DISCUSSION

A. Standard of Review

When ruling on a 12(b)(6) motion, the Court must accept the facts set forth in the complaint as true. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007). A complaint survives a motion to dismiss only if the plaintiff alleges sufficient factual matter to state a claim for relief that is plausible on its face, and he must state more than "unadorned, the-defendant-unlawfully-harmed-me accusations." *McCullough v. Finley*, 907 F.3d 1324, 1333 (11th Cir. 2018) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009)). He must also "plead more than labels and conclusions or a formulaic recitation of the elements of a cause of action," *id.*, such that the factual allegations contained in the complaint are "enough to raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 555.

When assessing a motion to dismiss for failure to state a claim, the Court employs a two-step framework. *McCullough*, 907 F.3d at 1333. First, the Court identifies and disregards allegations that are "no more than mere conclusions," since "[c]onclusory allegations are not entitled to the assumption of truth." *Id.* (quoting *Iqbal*, 556 U.S. at 679).

Second, the Court "assume[s] any remaining factual allegations are true and determine[s] whether those factual allegations 'plausibly give rise to an entitlement to relief.'" *Id.* (quoting *Iqbal*, 556 U.S. at 679).

Under Federal Rule of Civil Procedure 15(a)(2), the Court should freely grant leave to amend when justice so requires. However, the Court may deny leave to amend "(1) where there has been undue delay, bad faith, dilatory motive, or repeated failure to cure deficiencies by amendments previously allowed; (2) where allowing amendment would cause undue prejudice to the opposing party; or (3) where amendment would be futile." *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001). An amendment is futile, for example, "when the complaint as amended is . . . subject to dismissal because . . . it fails to state a claim for relief." *Chang v. JPMorgan Chase Bank, N.A.*, 845 F.3d 1087, 1094 (11th Cir. 2017) (quoting *Hall v. United Ins. Co. of Am.*, 367 F.3d 1255, 1262–63 (11th Cir. 2004)).

B. <u>Rhodes's Motion to Strike Plaintiff's Amended Complaint</u>

As a preliminary matter, Rhodes has moved to strike Plaintiff's Amended Complaint [Doc. 16] as untimely. The Federal Rules of Civil Procedure allow a party to amend a pleading once as a matter of right within either (a) 21 days after serving the original pleading; or (b) 21 days after the other party files a responsive pleading or a motion to dismiss the original pleading under Rule 12(b), (e), or (f), whichever is earlier. Fed. R. Civ. P. 15(a)(1). Once a party can no longer amend as a matter of right, it must

obtain the other party's consent or leave of court before amending its pleading. *Id.* at (a)(2).

Plaintiff filed her original complaint on September 10, 2018. Rhodes filed its Rule 12(b)(6) Motion to Dismiss on November 9, 2018 and has not yet filed an answer. Par filed its Rule 12(b)(6) Motion to Dismiss on November 30, 2018 and has also not filed an answer. Plaintiff filed her Amended Complaint on December 3, 2018. Therefore, Plaintiff filed her Amended Complaint 24 days after Rhodes filed its motion to dismiss and three days after Par filed its motion to dismiss.[3] While it is clear that the Court must strike the Amended Complaint as to Rhodes, it is unclear whether the Amended Complaint is binding on Par.

Courts differ on when the clock starts for amending as a matter of right in cases where there are multiple defendants who have filed responsive pleadings or Rule 12(b), (e), or (f) motions. For example, the District Court for the District of Columbia held that an amended complaint filed as a matter of right is effective on all defendants who have not filed a responsive pleading or defensive motion more than 21 days prior to the day the plaintiff filed the amended complaint.[4] *Villery v. District of Columbia*, 277 F.R.D. 218,

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[3] On December 3, 2018, Plaintiff requested and received a 14-day extension of time to file responses to Defendants' motions to dismiss pursuant to Local Rule 6.2. [Doc. 14]. The extension applied only to Plaintiff's briefs in response to the motions to dismiss and not to any time to amend as a matter of right. LR 6.2, MDGa ("In civil cases, the clerk of the court and his deputies are authorized to permit extensions of time to a date not to exceed fourteen (14) days for the filing of *briefs*.") (emphasis added).

[4] Thus, if Defendant A files an answer on Day 1, Defendant B files a motion to dismiss on Day 12, Defendant C files a motion to dismiss on Day 14, and Plaintiff files an amended complaint on Day 30, the amended

219 (D.D.C. 2011). However, other courts have held that an amended complaint filed as a matter of right is ineffective as to *all* defendants if it is filed more than 21 days after the *first* responsive pleading or defensive motion is filed.[5] *See, e.g.*, *Rubenstein v. Keshet Inter Vivos Tr.*, No. 17-61019-Civ-WILLIAMS/TORRES, 2017 WL 7792570, at *3 (S.D. Fla. Oct. 18, 2017); *Williams v. Black Entm't Television, Inc.*, No. 13-CV-1459(JS)(WDW), 2014 WL 585419, at *3–4 (E.D.N.Y. Feb. 14, 2014).

Given the unqualified language of the advisory committee notes to the latest version of the Rule, the Court agrees with the latter rationale that the ability to amend as a matter of right concludes 21 days after the first defendant files a responsive pleading or a motion under Rule 12(b), (e), or (f). *See* Fed. R. Civ. P. 15(a) advisory committee's note to 2009 amendment ("The 21-day periods to amend once as a matter of course after service of a responsive pleading or after service of a designated motion are not cumulative. If a responsive pleading is served after one of the designated motions is served, for example, there is no new 21-day period.").[6] In light of this standard, Plaintiff's

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complaint is not binding on Defendant A but is binding on Defendants B and C, who filed their motions to dismiss less than 21 days prior to the date Plaintiff filed her amended complaint.

[5] That is, if Defendant A files an answer on Day 1, Defendant B files a motion to dismiss on Day 12, Defendant C files a motion to dismiss on Day 14, and Plaintiff files an amended complaint on Day 30, the amended complaint must be stricken as to all Defendants because Plaintiff filed it more than 21 days after the first responsive pleading in the case was filed.

[6] But even if the Court were to agree with the *Villery* court and find that the amended complaint is binding on Par (who filed its motion to dismiss just three days prior to Plaintiff filing her amended complaint), the claims against Par as alleged in the untimely-filed amended complaint are just as deficient as those in the original complaint and the proposed amended complaint attached to Plaintiff's motion to amend, and the Court would have dismissed the claims sua sponte after giving Plaintiff notice of its intent to do so. *See*

amended complaint has no bearing on either Defendant since Rhodes filed its Rule 12(b)(6) motion to dismiss more than 21 days prior to Plaintiff amending as a matter of right, and Par's motion to dismiss did not commence a new 21-day amendment period. Therefore, the Court will consider both Defendants' motions to dismiss and Plaintiff's motion to amend to determine if either the original complaint or the proposed amended complaint states a claim.

C. Negligent Manufacturing Claim

From what the Court can glean from the complaints, Plaintiff seeks to state a claim for negligent manufacturing against both Defendants, despite there being no separate cause of action stated for such a claim. *See* [Doc. 19-1, ¶ 28] ("Rhodes and [Par] negligently marketed, manufactured, distributed, dispensed and prescribed the prescription drugs that caused the death of Tracy Faye Edge."). To succeed on a claim for negligent manufacturing, a plaintiff "must come forward with evidence that, among other things, there was a defect in the product when it left the manufacturer that was caused by the manufacturer's negligence." *Miller v. Ford Motor Co.*, 653 S.E.2d 82, 84 (Ga. Ct. App. 2007); *see also Sheats v. Kroger Co.*, 784 S.E.2d 442, 446 (Ga. Ct. App. 2016). Here, Plaintiff merely asserts that "opioids are not safe" and that Defendants' drugs are "dangerous," but the Court cannot find a single allegation in either the original complaint or the proposed

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Surtain v. Hamlin Terrace Found., 789 F.3d 1239, 1248 (11th Cir. 2015) (per curiam) ("Prior to dismissing an action on its own motion, a court must provide the plaintiff with notice of its intent to dismiss and an opportunity to respond.").

amended complaint that specifically identifies the dangerous qualities that were *inherent* in the drugs that killed Ms. Edge at the moment they left Defendants' facilities. At most, Plaintiff's complaints allege that an intervening factor made the drugs dangerous (e.g. overuse and/or taking them with certain other drugs). In the absence of an allegation of an inherent defect in her complaints, Plaintiff fails to allege facts to support the essential elements of a negligent manufacturing claim and, in doing so, fails to state a claim.

D. <u>Failure-to-Warn Claim</u>

In her complaints, Plaintiff also alleges that Defendants failed to warn of their drugs' adverse effects and of opioid toxicity in general. Defendants argue that this failure-to-warn claim is preempted by federal law and cite *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In *Mensing*, the Supreme Court held that federal law requires manufacturers of generic prescription drugs to ensure that their drug labels are identical to those of the name-brand drugs from which the generics are derived, and it prohibits those manufacturers from unilaterally changing existing, approved labels. 564 U.S. at 613–17. Thus, federal law preempts state-law failure-to-warn claims against generic drug manufacturers because manufacturers would be incapable of complying with federal law if their warnings—or lack thereof—were considered inadequate under state law. *Id.* at 618.[7]

[7] The Court reiterated the *Mensing* holding in *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013).

Rhodes's morphine and Par's amitriptyline are both generic medications covered by the federal laws discussed in *Mensing*.[8] Nevertheless, Plaintiff alleges in her proposed amended complaint that Defendants "cannot preempt liability by merely claiming generic status" and that generic medications "are not allowed to hide under the auspices of generic status for liability." [Doc. 19-1, ¶¶ 52, 53]. Plaintiff offers no legal support for her contentions, and in the absence of some basis for her claims, the Court agrees with Defendants that, no matter how artfully pled, Plaintiff fails to state a claim for failure to warn because such a claim is preempted by federal law.

E. <u>Fraud Claim</u>

Plaintiff also seeks to state a claim for fraud or negligent misrepresentation against Defendants by alleging that they "directly marketed to spread false and deceptive statements about the risks and benefits of opioid use," "claim in literature that opioids are safer than a Tylenol," "encourage doctors to write prescriptions for opioids . . . [by] touting the opioids as safe and non-habit forming," and "deceptively marketed the opioids as being less addictive and safer," even though such "medical marketing . . . is false, misleading and causes harm." [*Id.* at ¶¶ 16, 59–61]. Pretermitting whether Plaintiff

[8] Plaintiff does not allege that the drugs at issue in this case were generics, but the Court obtained this information from photos attached to Defendants' motions to dismiss. The Court may consider documents not attached to the complaint without taking judicial notice of them and without converting the motion into one for summary judgment if the documents are "(1) central to the plaintiff's claim, and (2) [their] authenticity is not challenged." *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 811 (11th Cir. 2015). Plaintiff does not dispute the generic status of Rhodes's morphine and Par's amitriptyline, and that status is central to the determination of the duties owed by Defendants to the public.

has pled the fraudulent/negligent misrepresentations with particularity as required under Federal Rule of Civil Procedure 9 is Plaintiff's failure to even plead the essential elements of either a fraud or negligent misrepresentation claim, which both require proof of justifiable or reasonable reliance and causation. Plaintiff has not pled any facts showing that Ms. Edge or her doctors relied on any representations made by Defendants in taking or prescribing morphine and amitriptyline. But even if she had done so, her conclusory statements that "[t]he false medical marketing and advertising by [Defendants] caused harm to [Ms.] Edge" and that "[b]ut for . . . [Defendants'] deceptive and false marketing of the generic opioids, [Ms.] Edge suffered damages and death" are factually insufficient to allege the essential element of causation. As such, Plaintiff has failed to state a claim for either fraud or negligent misrepresentation in either of her complaints.

F. RICO, Controlled Substances Act, and OBRA

To the extent Plaintiff seeks to allege any claims under the Racketeer influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961–1968 ("RICO"); the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*; or the Omnibus Budget Reconciliation Act of 1990, Pub. L. 101–508, 104 Stat. 1388 ("OBRA 90"), the Court has previously explained to Plaintiff that such claims are untenable. *See Allen v. Endo Pharm., Inc.*, No. 5:18-cv-00132-TES, ECF No. 74 (M.D. Ga. Aug. 23, 2018).[9]

[9] The Court may take judicial notice of its prior orders without converting a motion to dismiss into one for summary judgment. *Universal Express, Inc. v. SEC*, 177 F. App'x 52, 53 (11th Cir. 2015) (per curiam). The

CONCLUSION

For the reasons stated above, Plaintiff's original complaint is binding on Defendants, and Plaintiff was required to seek the Court's approval before amending her claims against them. By filing her Amended Complaint [Doc. 16] without such approval, Plaintiff did not comply with the requirements to amend as a matter of right under Federal Rule of Civil Procedure 15, and the Court therefore **GRANTS** Rhodes's Motion to Strike [Doc. 17].

The Court also finds that Plaintiff's original complaint fails to state a claim and that the proposed amended complaint attached to Plaintiff's Motion to Amend is likewise deficient. Accordingly, Defendants' Motions to Dismiss [Docs. 4, 13] are **GRANTED**, and Plaintiff's Motion to Amend [Doc. 19] is **DENIED as futile**. Plaintiff's Complaint [Doc. 1] is therefore **DISMISSED without prejudice**.

SO ORDERED, this 11th day of February, 2019.

s/Tilman E. Self, III
TILMAN E. SELF, III, Judge
UNITED STATES DISTRICT COURT

Court therefore **GRANTS** Rhodes's Motion Seeking Judicial Notice [Doc. 5], relating to the Court's prior orders and to which Plaintiff filed no response.