UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

Kyle, et al.

v. Case No. 19-cv-646-PB
Opinion No. 2020 DNH 058

Linden Care, LLC, and
Rochester Drug Co-Operative, Inc.

MEMORANDUM AND ORDER

Plaintiffs in these consolidated cases[1] allege they became dependent on a prescribed under-the-tongue fentanyl spray, Subsys, and later suffered withdrawal symptoms. They have brought negligence claims against Linden Care, LLC ("Linden Care"), the concierge pharmacy that filled their prescriptions, and Rochester Drug Co-Operative, Inc. ("RDC"), the wholesale drug distributor that filled Linden Care's orders for Subsys. Linden Care and RDC have responded with motions to dismiss arguing both that plaintiffs failed to plead viable negligence claims and that their claims are barred by the New Hampshire statute of limitations for personal actions. RDC recently filed

[1] Plaintiffs initially filed individual cases: Jeffrey and Polly Kyle (19-cv-646-PB); Pamela Langlois (19-cv-722-LM); Paul Dooley (19-cv-898-JL); and Colleen Perry (19-cv-723-JL). The cases have been consolidated for pretrial purposes with Kyle et al. v. Linden Care, LLC, Rochester Drug Co-Operative, Inc., 19-cv-646-PB, the named case.

for bankruptcy protection. Def. RDC's Suggestion of Bankruptcy, Doc No. 45. Accordingly, in this Memorandum and Order, I resolve only Linden Care's motions to dismiss.

I. STANDARD OF REVIEW

To overcome a motion to dismiss under Rule 12(b)(6), the plaintiff must make sufficient factual allegations to "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)). Under this plausibility standard, the plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. This pleading requirement demands "more than a sheer possibility that [the] defendant has acted unlawfully," or "facts that are merely consistent with [the] defendant's liability." Id. Although the complaint need not set forth detailed factual allegations, it must provide "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Id.

In evaluating the pleadings, I excise any conclusory statements from the complaint and credit as true all non-conclusory factual allegations and reasonable inferences drawn from those allegations. Ocasio-Hernández v. Fortuño-Burset, 640

F.3d 1, 12 (1st Cir. 2011). I "may also consider 'facts subject to judicial notice, implications from documents incorporated into the complaint, and concessions in the complainant's response to the motion to dismiss.'" Breiding v. Eversource Energy, 939 F.3d 47, 49 (1st Cir. 2019) (quoting Arturet-Vélez v. R.J. Reynolds Tobacco Co., 429 F.3d 10, 13 n.2 (1st Cir. 2005)).

Motions to dismiss may be based on affirmative defenses such as a statute of limitations defense. Rodi v. S. New Eng. Sch. of Law, 389 F.3d 5, 17 (1st Cir. 2004) (citing LaChapelle v. Berkshire Life Ins. Co., 142 F.3d 507, 509 (1st Cir. 1998)). When considering a statute of limitations defense presented in a Rule 12(b)(6) motion, I must determine "whether the complaint and any documents that properly may be read in conjunction with it show beyond doubt that the claim asserted is out of time." Id.; accord LaChapelle, 142 F.3d at 509 ("Granting a motion to dismiss based on a limitations defense is entirely appropriate when the pleader's allegations leave no doubt that an asserted claim is time-barred.").

II. BACKGROUND

A. Federal Statutory and Regulatory Scheme

Plaintiffs refer to the regulatory scheme of the Federal Food, Drug, and Cosmetic Act ("FDCA") when alleging negligence

on the part of Linden Care. The FDCA and its amendments empower the Food and Drug Administration ("FDA") to regulate food, drugs, medical devices, and cosmetics. See 21 U.S.C. § 301 et seq. The FDA oversees Risk Evaluation and Mitigation Strategy ("REMS") programs under the FDA Amendments Act of 2007, which amended the FDCA. 21 U.S.C. § 355-1; see Questions and Answers: FDA Approves a Class Risk Evaluation and Mitigation Strategy (REMS) for Transmucosal Immediate-Release Fentanyl (TIRF) Medicines ("Q&A"), FDA (July 9, 2015), https://www.fda.gov/drugs/information-drug-class/questions-and-answers-fda-approves-class-risk-evaluation-and-mitigation-strategy-rems-transmucosal. "A REMS is a risk management plan that uses minimization strategies beyond approved labeling to manage serious risks associated with a drug." Q&A, supra. It "can include a Medication Guide or patient package insert, communication plan, one or more elements to assure safe use, an implementation system, and a timetable for submission of the REMS assessment." Id.

The FDA approved a REMS program, effective in March 2012, for a class of drugs known as transmucosal immediate-release fentanyl ("TIRF") medicines. Id. These "medicines are used to manage breakthrough pain in adults with cancer who are routinely taking other opioid pain medicines around-the-clock for pain." Id. The TIRF REMS Program provides several safeguards designed

to prevent opioid "misuse, abuse, addiction, overdose, and serious complications." About the TIRF REMS Program ("About the Program"), TIRF REMS Access, https://www.tirfremsaccess.com/TirfUI/rems/about.action (last (allowing participants in the program to register and manage their TIRF REMS Account). "Patients must complete a Patient-Prescriber Agreement Form before they can be prescribed a TIRF medicine . . . ." Id. Outpatient pharmacies are also unable to dispense TIRF medicines

> unless an authorized pharmacist has reviewed the TIRF REMS Access Education Program and successfully completed the Knowledge Assessment and enrollment form. Enrolled pharmacies can only dispense prescriptions for TIRF medicines if the prescriber and pharmacy are enrolled and active and the patient has not been inactivated in the program.

Id.

Subsys is a TIRF medicine that is approved only "for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." FDA Approval Letter for Subsys (Jan. 2, 2012) at 1, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202788Orig1s000Approv.pdf; see, e.g., Doc. No. 17 at ¶ 9. The FDA caps the initial dosage at 100 mcg, followed by carefully titrated higher dosages in the smallest increments possible to manage the patient's pain. "TIRF Products REMS," TIRF REMS Access Program

Education Program for Prescribers and Pharmacists, at 19, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202788Orig1s000Rems.pdfa/2012/202788Orig1s000Rems.pdf; accord Doc. No. 17 at 2 ¶ 10.

B. Allegations in the Amended Complaints

Plaintiffs Jeffrey Kyle, Paul Dooley, Colleen Perry, and Pamela Langlois were prescribed Subsys by Christopher Clough, a former physician assistant at the PainCare clinic in Somersworth, New Hampshire. Kyle Am. Compl., Doc. No. 17 at 2 ¶¶ 4–5, 7–8; Perry Am. Compl., Doc. No. 33 at 1–2 ¶¶ 4–9; Dooley Am. Compl. at 2 ¶¶ 4–5, 7–9, 19-cv-898-PB (D.N.H. Nov. 14, 2019), ECF No. 13; Langlois Am. Compl. at 2 ¶¶ 4–8, 19-cv-722-PB (D.N.H. Nov. 6, 2019), ECF No. 17. Linden Care filled all of the plaintiffs' Subsys prescriptions.

Plaintiffs allege that when Linden Care filled plaintiffs' prescriptions, it certified that it knew it could only fill Subsys prescriptions for patients with medical conditions warranting its prescription . . . [and] that it would comply with the dosage instructions . . . ." E.g., Doc. No. 17 at 7 ¶ 42. Further, plaintiffs allege that "Linden Care knew that it could not dispense TIRF[]REMS drugs to patients who were not enrolled in the TIRF[]REMS program, and . . . under the [CSA] that it could not dispense . . . Fentanyl without physical

possession of the original prescription." E.g., Doc. No. 17 at 8 ¶ 42. Nevertheless, plaintiffs allege that Linden Care repeatedly filled their Subsys prescriptions even though they were not eligible to receive them under the TIRF REMS Access Program.

C. Plaintiffs' Injuries

Because plaintiffs' claims against Linden Care require a fact-intensive inquiry, the events giving rise to each plaintiff's alleged injuries are discussed below in detail.

1. Jeffrey Kyle

Jeffrey Kyle received his first shipment of Subsys from Linden Care in July 2013. Doc. No. 17 at 3 ¶ 12. He "was given an initial dose of 600 mcg[,]" which is six times higher than the maximum initial dose allowed by the TIRF REMS Program. Doc. No. 17 at 2 ¶ 10. Although the FDA approved Subsys only for cancer patients' breakthrough pain, Kyle was not being treated for cancer-related pain, but rather for "lower extremity pain" in his legs. Doc. No. 17 at 2 ¶ 4. He also did not sign the required TIRF REMS consent form before receiving his Subsys prescription, Doc. No. 17 at 2 ¶ 11, and Linden Care failed to confirm that valid forms had been submitted, Doc. No. 17 at 8 ¶¶ 44–45. In fact, an unsigned form was submitted for Kyle after his first prescription was filled. Doc. No. 17 at 8 ¶ 45 (emphasis added). Despite these warning signs, Linden Care

continued to fill subsequent "prescriptions without proper titration practices." Doc. No. 17 at 8 ¶ 43; accord Doc. No. 17 at 3 ¶ 13 ("Over the next four months[,] . . . Clough increased the prescribed dose . . . without medical justification, from 600 mcg to 800 mcg to 1600 mcg . . . .").

As a result, "Kyle became highly dependent on Subsys." Doc. No. 17 at 3 ¶ 14. When his medical insurance provider refused to pay for Subsys in September 2014, Doc. No. 17 at 3 ¶ 15, "Kyle began experiencing severe symptoms of withdrawal[,]" including "sweating, abdominal discomfort, chills, restless legs, hot flashes[,] and vomiting. He felt like [he] was going to die. He felt extreme pain all over his body and was in a state of high anxiety and panic," Doc. No. 17 at 3 ¶ 16. Kyle filed his initial complaint on June 13, 2019.

2. Paul Dooley

Paul Dooley received his first shipment of Subsys from Linden Care in October 2013. Dooley Am. Compl., supra, at 3 ¶ 14. His initial dose was "originally written" for 200 mcg but "was doubled without explanation to 400 mcg before the drug was dispensed. This initial dose . . . was [four] times more than the FDA[-]mandated initial dose of 100 mcg." Dooley Am. Compl., supra, at 2 ¶ 8. Dooley was not prescribed Subsys for cancer-related pain, either. See Dooley Am. Compl., supra, at 2 ¶ 4. Clough increased Dooley's prescription on October 21, 2013 and

on November 11, 2013, at which point Dooley was on the highest dose possible, 1600 mcg. Dooley Am. Compl., supra, at 3 ¶¶ 17–19. He, too, "became highly dependent on Subsys[,]" experiencing "zombie[-]like symptoms" while on the medication. Dooley Am. Compl., supra, at 3 ¶ 19. Clough took Dooley off the highest dose possible on August 18, 2014 "without any downward titration[,]" resulting in Dooley suffering from "severe withdrawal symptoms . . . ." Dooley Am. Compl., supra, at 4 ¶¶ 21–22. Dooley filed his initial complaint on September 4, 2019.

3. Colleen Perry

Colleen Perry received her first shipment of Subsys from Linden Care "within a few days" of her June 27, 2013 visit with Clough. Doc. No. 33 at 2 ¶ 7, 3 ¶ 13. He prescribed Subsys to her despite her protests, Doc. No. 33 at 2 ¶ 8, and even though he was not treating her for cancer-related pain, see Doc. No. 33 at 1 ¶ 4. Her initial dosage was also inappropriately high at 400 mcg. Doc. No. 33 at 2 ¶ 8. Clough increased her dosages on July 19, 2013; September 23, 2013; and February 9, 2014, by which point "she was on the maximum dosage of 1600 mcg . . . ." See Doc. No. 33 at 3 ¶¶ 15–16. She, too, became "highly dependent on Subsys. On several occasions she lost consciousness . . . and had to be revived . . . . She would fall asleep at work, at dinner[,] and during conversations." Doc. No. 33 at 3 ¶ 17. Even though she asked Clough to reduce her dose, he refused

to do so until November 24, 2014. Doc. No. 33 at ¶¶ 17–18. She then had a new physician who weaned her off Subsys gradually by March 27, 2015. Doc. No. 33 at 4 ¶ 21.[2] Later, she had a third physician who put her back on Subsys but took her off by December 1, 2015.[3] Doc. No. 33 at 4 ¶ 22. Perry filed her initial complaint on July 9, 2019.

4. Pamela Langlois

Pamela Langlois received her first shipment of Subsys from Linden Care "within a few days of" her July 29, 2013 visit to Clough. Langlois Am. Compl., supra, at 2 ¶¶ 7, 11. Clough did not discuss the prescription with Langlois and gave her an initial dose of 400 mcg. Langlois Am. Compl., supra, at 2 ¶¶ 7, 10. She was not being treated for cancer-related pain. See Langlois Am. Compl., supra, at 2 ¶ 4. She "was never shown, nor did she sign[,] a TIRF[]REMS enrollment form." Langlois Am. Compl., supra, at 3 ¶ 13. Instead, her "name is typed into this form in place of the necessary signature, and the form is dated . . . several days after [she] had already received her first

[2] Despite this physician's attempt to wean Perry off Subsys, she still suffered withdrawal after her prescription ended "on or about March 27, 2015." Doc. No. 33 at 4 ¶ 22.

[3] Perry does not explicitly allege that Linden Care filled the prescriptions not written by Clough or that these prescriptions should have raised the same red flags under the TIRF REMS Program.

prescription of Subsys." Langlois Am. Compl., supra, at 3 ¶ 13. Clough subsequently increased her prescription on or around November 2013, December 2013, and on a third occasion at a time not specified, at which point she was taking the maximum possible dose, 1600 mcg. Langlois Am. Compl., supra, at 3 ¶¶ 16–17. Just like Kyle, Dooley, and Perry, Langlois also "became highly dependent on Subsys. On several occasions she lost consciousness due to the side effects of Subsys and had to be revived by her husband who thought she had stopped breathing." Langlois Am. Compl., supra, at 3 ¶ 18. Once, Langlois's "husband nearly called 911, because [her] breathing became very shallow and he could not get [her] to 'wake up.'" Langlois Am. Compl., supra, at 4 ¶ 18. Clough then cut her prescription sharply, without titration, in July 2014 and completely cancelled her prescription around October 23, 2014 without any warning. Langlois Am. Compl., supra, at 4 ¶¶ 19–20. She "experienced serious withdrawal symptoms" due to the abrupt decreases in dosages, including "diarrhea, cramping, cold sweats, significant increases in pain, depression[,] and suicidal ideations." Langlois Am. Compl., supra, at 4 ¶ 21. Langlois filed her initial complaint on July 9, 2019.

III. ANALYSIS

Linden Care argues that plaintiffs have failed to plead cognizable negligence claims against it because their complaints do not sufficiently allege the elements of negligence.[4] In the alternative, Linden Care invokes the New Hampshire statute of limitations as an affirmative defense. I address each argument in turn.

A. Insufficient Pleading

Linden Care asserts that the complaints do not allege that it breached any duty it owed to the plaintiffs, e.g., Def.'s Mem. of Law in Support of Mot. to Dismiss Pls.' Am. Compl. in Lieu of Answer, Doc. No. 19-1 at 11-14, but this assertion is clearly incorrect.

Plaintiffs allege that Linden Care "had a duty to abide by safety standards of care for their [sic] industry[,]" e.g., Doc. No. 17 at 12 ¶ 61, as well as "a duty to use professional skill, knowledge[,] and care from its education, training[,] and experience[,] and to abide by the standards of its profession;

[4] Linden Care also mistakenly claims that the plaintiffs have improperly pleaded an implied private right of action under the Comprehensive Drug Abuse Prevention and Control Act of 1970, better known as the Controlled Substances Act ("CSA"), see 21 U.S.C. § 801 et seq. This argument is unavailing because plaintiffs have expressly disclaimed that they are seeking to enforce an implied private right of action. See, e.g., Pls.' Obj. to Def., Linden Care's Mot. to Dismiss Am. Compl., Doc. No. 25 at 8 ¶ 30.

and a duty to comply with applicable federal and state laws when filling, dispensing, and authorizing . . . Subsys prescriptions," e.g., Doc. No. 17 at 12 ¶¶ 61–62. They also allege that Linden Care breached its duty "when it failed to report suspicious activity" surrounding their Subsys prescriptions, e.g., Doc. No. 17 at 12 ¶ 63; fulfilled prescriptions for Subsys that plaintiffs did not need based on their diagnoses, e.g., Doc. No. 17 at 12 ¶ 64; "accept[ed] faxed prescriptions[,]" instead of demanding original copies from Clough, e.g., Doc. No. 17 at 13 ¶ 65; "fail[ed] to verify" patients' proper TIRF REMS enrollments, e.g., Doc. No. 17 at 13 ¶ 66; filled initial prescriptions that exceeded the TIRF REMS limit for initial doses, e.g., Doc. No. 17 at 13 ¶ 67; and continued to increase the doses without proper titration, e.g., Doc. No. 17 at 13 ¶ 68.

These allegations are plainly sufficient to support plaintiffs' negligence claims against Linden Care if the duties alleged are ones that New Hampshire is prepared to recognize. Because Linden Care has not presented a developed argument that New Hampshire law does not recognize the duties on which plaintiffs' claims are based, I decline to take that issue up on my own. Accordingly, I deny Linden Care's motion to dismiss on this basis without prejudice to the company's right to raise the matter again on summary judgment.

B. Statute of Limitations

Linden Care argues in the alternative that the complaints must be dismissed because they are barred by New Hampshire's three-year statute of limitations for personal actions, N.H. Rev. Stat. Ann. § 508:4. That statute specifies that the limitation period for personal actions begins to run "from the act or omission complained of" unless the discovery rule applies. Id. Under the discovery rule, "when the injury and its causal relationship to the act or omission were not discovered and could not reasonably have been discovered at the time of the act or omission," the plaintiff must bring suit "within [three] years of the time the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, the injury and its causal relation to the act or omission complained of." Id.; accord Beane v. Dana S. Beane & Co., P.C., 160 N.H. 708, 712 (2010) (quoting Conrad v. Hazen, 140 N.H. 249, 252 (1995)) ("[A] cause of action . . . does not accrue 'until the plaintiff discovers, or in the exercise of reasonable diligence should have discovered, both the fact of an injury and the cause thereof.'"). "The defendant bears the burden of proving that the defense applies by showing that the action was not filed within the limitation period. The burden then shifts to the plaintiff to prove that the discovery rule saves the claims." Mareld Co.,

Inc. v. New Eng. Tel. & Tel. Co., No. 16-cv-390-PB, 2018 WL 6251342, at *3 (D.N.H. Nov. 28, 2018) (citations omitted).

Although plaintiffs plainly waited more than three years from Linden Care's last allegedly injurious act to bring their claims, I cannot determine on the present record whether their claims are time-barred. This is because plaintiffs have invoked the discovery rule, and whether the rule applies turns on issues of fact that have not yet been properly developed. See id. (recognizing that "[w]hether the plaintiff exercised reasonable diligence in discovering the injury and its causal relationship to the defendant's conduct is a question of fact").

Linden Care relies on Keshishian v. CMC Radiologists, 142 N.H. 168 (1997) for the proposition that the court must decide whether a plaintiff is entitled to benefit from the discovery rule when the court is presented with a Rule 12(b)(6) motion asserting a statute of limitations defense. This argument is based on a misreading of Keshishian. That case merely provides that the applicability of the discovery rule must be decided by the judge rather than the jury. See Keshishian, 142 N.H. at 179–81. It does not purport to require a judge decide the issue on a Rule 12(b)(6) motion. Instead, as First Circuit law clearly recognizes, the only time when it is appropriate to enforce a statute of limitations defense when ruling on a Rule 12(b)(6) motion is when it is "beyond doubt" that the claim is time-

barred. Rodi, 389 F.3d at 17; accord LaChapelle, 142 F.3d at 509. This standard has not been met given the current state of the pleadings. Accordingly, I deny Linden Care's motions to dismiss without prejudice to its right to raise the statute of limitations issue again either by filing a properly supported motion for summary judgment or by requesting an evidentiary hearing on the issue.

IV. CONCLUSION

For the foregoing reasons, I deny Linden Care's motions to dismiss (Doc. Nos. 19, 23, 24, 37) without prejudice. RDC's motions to dismiss (Doc. Nos. 21, 22, 38) are stayed during its bankruptcy proceeding (Doc. No. 45), pursuant to 11 U.S.C. § 362(a).

SO ORDERED.

/s/ Paul J. Barbadoro
Paul J. Barbadoro
United States District Judge

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