UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

LISA POLSON, *Plaintiff*, v. ASTRAZENECA LIMITED PARTNERSHIP; ASTRAZENECA PHARAMCEUTICALS LIMTIED PARTNERSHIP *Defendants.*	: : : : : : : :	Case No. 3:21-CV-00755 (OAW) APRIL 4, 2023

RULING ON DEFENDANT'S MOTION TO DISMISS

This case arises out of a severe and adverse reaction to the prescription drug medication known as "Movantik." Plaintiff Lisa Polson ("Plaintiff") brings this action against the drug's manufacturer, AstraZeneca Pharmaceuticals Limited Partnership ("AstraZeneca").[1] Plaintiff alleges that as a result of ingesting Movantik she suffered life-threatening injuries, including internal bleeding from the perforation of her intestine, and septic shock. In her five-count Amended Complaint, she alleges state law claims under the Connecticut Product Liability Act ("CPLA"): the failure to warn (Count One); defective design of the drug (Count Two); breach of express warranty (Count Three), breach of the implied warranty of fitness for a particular purpose (Count Four), and breach of the implied warranty of merchantability (Count Five). Am. Compl., ECF No. 24. AstraZeneca has moved to dismiss all counts of the Amended Complaint on the grounds of federal preemption. Mem. of Law at 1, ECF No. 31. In recognition of the preemption issue, Plaintiff "concedes that all counts of the complaint can be dismissed." Pl.'s Opp. at 2, ECF No. 40. Plaintiff, however, requests leave to amend the complaint so that she may

[1] Plaintiff's Amended Complaint names as an additional defendant, AstraZeneca Limited Partnership ("AZ LP"). However, AZ LP no longer exists, as it merged into AstraZeneca in 2018. Mot. to Dismiss at 1 n.1, ECF No. 30.

replead with a single cause of action which clarifies her claim for defective design of the drug. *Id.* Because the proposed amendment would not defeat the federal preemption issue, Plaintiff's request to replead is denied. Accordingly, the motion to dismiss hereby is **GRANTED** with prejudice, and without leave to amend. The clerk of court is directed to terminate this action.

I. BACKGROUND

Movantik (naloxegol) is a prescription drug medication used to treat constipation caused by opioid pain medicine in adult patients with chronic non-cancer pain. Am. Compl. at p. 1–2. The Food and Drug Administration ("FDA") approved Movantik for such use in 2014. *See* Movantik Prescribing Information Sheet, ECF No. 31-1.[2]

On March 28, 2018, Plaintiff was prescribed Movantik by her doctor, Jonathan Kost, M.D. Am. Compl. at ¶ 29. On the morning of May 2, 2018, Plaintiff took Movantik as prescribed, and became very ill within a short period of time. *Id.* at ¶ 30. Plaintiff experienced extreme abdominal pain, vomiting, blood in the toilet, chills, and a high fever. *Id.* at ¶¶ 30–31. She called for an ambulance and was transported to a clinic in Guilford, CT. *Id.* at ¶ 32–33. After bloodwork and a CT scan revealed a perforation of her intestine, Plaintiff immediately was transferred to the emergency room at Yale New Haven Hospital. *Id.* at ¶¶ 32–36. Plaintiff was rushed into emergency surgery with the principal diagnosis

[2] Although the Prescribing Information Sheet is not attached to the Amended Complaint, the court takes judicial notice of the document as a public record of the FDA. *See Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47 (2d Cir. 1991) (noting that a district court may take judicial notice of public records where a plaintiff chooses not to attach to the complaint a document in which it "solely relies" and which is "integral to the complaint"); *Physicians Healthsource, Inc. v. Boehringer Ingelheim Pharms., Inc.*, 847 F.3d 92, 94 (2d Cir. 2017) (recognizing that district court took judicial notice of FDA records in ruling on motion to dismiss). Plaintiff does not object to court taking judicial notice, Pl.'s Opp. at 1–2, and the court finds that the Prescribing Information Sheet is integral to Plaintiff's failure to warn claim.

of "diverticulitis of her large intestine with perforation with bleeding and septic shock." *Id.* at ¶ 37.

Plaintiff alleges that AstraZeneca failed to adequately warn Plaintiff, her physicians, and the general public of the risks of Movantik. *Id.* at ¶ 44. She also alleges that the drug is defective in its "design or formulation," *id.* at ¶ 52, and that AstraZeneca expressly warranted that Movantik was safe for its intended use. *Id.* at ¶ 57. Plaintiff further alleges that she relied on both express and implied warranties that AstraZeneca would provide a drug that was safe for use. *Id.* at ¶¶ 66, 72. Plaintiff seeks damages for her injuries, and alleges that she will continue to incur in the future substantial expenses for medical care, diagnostic testing, treatment, and potential surgery. *Id.* at ¶ 39.

II. STANDARD OF REVIEW

To withstand a motion to dismiss brought pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The plausibility standard is not a probability requirement; the pleading must show, not merely allege, that the pleader is entitled to relief. *Id.* Legal conclusions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not entitled to a presumption of truth. *Id.* "To state a plausible claim, the complaint's '[f]actual allegations must be enough to raise a right to relief above the speculative level.'" *Nielsen v. AECOM*

Tech. Corp., 762 F.3d 214, 218 (2d Cir. 2014) (quoting *Twombly*, 550 U.S. at 555). However, when reviewing a motion to dismiss, the court must draw all reasonable inferences in the non-movant's favor. *Graziano v. Pataki*, 689 F.3d 110, 114 (2d Cir. 2012). The review is confined to the facts alleged in the operative complaint. *See Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007).

III. FDCA Preemption

The Constitution, through the Supremacy Clause, establishes that federal law "shall be the supreme Law of the Land" notwithstanding any state law to the "[c]ontrary." U.S. Const., Art. VI, cl. 2. Courts enforce the Supremacy Clause through the doctrine of preemption, whereby a federal law will supersede (or "preempt") conflicting state laws. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011). Conflict preemption exists when "compliance with both federal and state regulations is a physical impossibility." *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

The FDCA is a federal law which regulates the manufacture, use, or sale of drugs. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005) (internal quotation marks omitted). A drug manufacturer may not market a new drug without first submitting a new drug application ("NDA"), and receiving approval from the U.S. Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). The FDA is required to refuse any NDA where the drug manufacturer fails to demonstrate that the drug "is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). If an NDA is approved, the drug manufacturer may not unilaterally

change the label absent further FDA approval. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); *see also* 21 C.F.R. § 314.70(b).

The Second Circuit has held that "[d]esign and manufacturing defect claims . . . under state law are preempted by federal law if the manufacturer would require prior FDA approval to comply with those [state law] duties." *Ignacuinos v. Boehringer Ingelheim Pharms. Inc*, 8 F.4th 98, 101 (2d Cir. 2021). For example, if a state law requires a manufacturer to make a change in a drug design which has "a substantial potential to have an adverse effect," 21 C.F.R. § 314.70(b)(1), or a change which is enumerated in § 314.70(b)(2), the state law is preempted because federal regulation requires prior FDA approval for such drug changes. *See Ignacuinos*, 8 F.4th at 101 (preempting plaintiffs' state law design and manufacturing defect claims where the changes required under state law would implicate § 314.70(b)(2)). An exception to this rule is the Changes Being Effected ("CBE") regulation, which allows a manufacturer to strengthen a drug's warning label, without prior FDA approval, "to reflect newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii); *Wyeth*, 555 U.S. at 573 (state law not preempted where CBE regulation allowed drug manufacturer to "unilaterally strengthen its warning" and thus compliance with both state and federal was not "impossible"). Thus, preemption of a state law design defect claim necessarily depends on (1) the type of defect alleged, and (2) whether curing such defect pursuant to a state law duty would require prior FDA approval. *See Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 182 (S.D.N.Y. 2016) (state law claim for design defect may be preempted depending on the "nature of the plaintiff's . . . claim").

IV. DISCUSSION

AstraZeneca argues that each count of the Amended Complaint should be dismissed because all of Plaintiff's claims are preempted by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq*. In response to AstraZeneca's motion to dismiss, Plaintiff submits a two-page opposition brief admitting that she amended the complaint "in an unsuccessful attempt to avoid preemption," and in which "she concedes that all counts of the complaint can be dismissed." Pl.'s Opp. at 2. Plaintiff, however, requests that the court dismiss Count Two without prejudice so that she may re-plead her strict liability claim for defective design. *Id.* AstraZeneca argues that any amendment would be futile because a state law claim for design defect is preempted by the FDCA.

Absent any objection from Plaintiff, all counts of the Amended Complaint hereby are **DISMISSED.** Accordingly, this ruling is limited to whether Plaintiff is permitted to replead her state law claim for design defect under Count Two.

a) Count Two – Design Defect

Count Two is entitled, "Violation of CPLA: Strict Liability – Defective Design." Am. Compl. at Count II, ECF No. 24. Plaintiff alleges that AstraZeneca manufactured Movantik, and placed it into the stream of commerce, "in a defective and unreasonably unsafe condition." *Id.* at ¶ 51. Plaintiff does not indicate how Movantik is defective. Instead, she states in a conclusory fashion that the drug is defective simply in its "design or formulation." *Id.* at ¶ 52. Even in the absence of preemption, the court would have been obligated to dismiss this count for failure to adhere to the court's pleading standards. *Ashcroft v. Iqbal*, 556 U.S. at 678, ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

In opposing AstraZeneca's motion to dismiss, Plaintiff seeks to amend Count Two so that she may allege a defective design claim under Connecticut's consumer expectation test. Under Connecticut law, a product liability claim based on a design defect theory, requires a plaintiff to prove the following elements:

> (1) the defendant was engaged in the business of selling the product; (2) *the product was in a defective condition unreasonably dangerous to the consumer or user*; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in condition. *Izzarelli v. R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 184–85 (2016) (emphasis in original).

The consumer expectation test allows a plaintiff to prove the second element, that a defect is "unreasonably dangerous," if it "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Bifolck v. Philip Morris, Inc.*, 324 Conn. 402, 436 (2016). The product must fail to meet "minimum safety expectations" of that product when used in an "intended or reasonably foreseeable manner." *Id.* Plaintiff seeks to amend Count Two to allege that Movantik fails to meet such minimum safety expectations and to allege that the drug is dangerous to an extent beyond that which would be contemplated by the ordinary consumer. Pl.'s Opp. at 2, ECF No. 40. AstraZeneca contends that "any amendment" of Plaintiff's state law design defect claim is preempted by the FDCA. Def.'s Reply at 2, ECF No. 43.

The court finds that Plaintiff's proposed amendment is preempted by the FDCA, and therefore denies leave to replead Count Two of her complaint. *See Glover v. Bausch & Lomb Inc.*, 43 F.4th 304, 306 (2d Cir. 2022) (affirming district court's denial of leave to amend complaint where proposed amendment is futile). In seeking to establish that

AstraZeneca's drug is "unreasonably dangerous" because it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer," Plaintiff attempts to use state law to contradict the findings of the FDA. When approving AstraZenca's NDA, the FDA was required to find that Movantik is safe for use "under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d). Of course, "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth*, 555 U.S. at 575. However, this is not an instance in which a plaintiff seeks to enforce a state law duty to strengthen a warning label beyond the labeling requirements of the FDA. *Id.* at 568– 571. Instead, Plaintiff seeks to hold AstraZeneca liable for a perceived defect with the drug's design, formulation, and composition. However, a drug manufacturer may not alter the composition of a drug without prior FDA approval. *See* 21 C.F.R. § 314.70(b)(2)(i) ("changes in the qualitative or quantitative formulation of the drug product" require a supplemental submission, and FDA approval). If state product liability law requires a drug manufacturer to alter the drug's formulation, but federal law requires those changes to be approved by the FDA, the state law must give way to federal law. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 490 (2013) (holding that "state-law design-defect claims . . . that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling."); *see also Ignacuinos*, 8 F.4th at 101 (design defect claim preempted where FDA approval is required to alter purported defect).

V. CONCLUSION

Accordingly, AstraZeneca's motion to dismiss (ECF No. 30) hereby is **GRANTED,** and Plaintiff's request for leave to amend hereby is **DENIED.** The Clerk of Court kindly is instructed to terminate this case.

IT IS SO ORDERED. Entered at Hartford, Connecticut, this 4th day of April, 2023.

/s/
OMAR A. WILLIAMS
United States District Judge