UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOAH MEDFORD, et al.,

Plaintiffs,

v.

EON LABS, INC., et al.,

Defendants.

Civil Action No. 20-00412

OPINION & ORDER

THIS MATTER comes before the Court by way of Defendants Eon Labs, Inc. ("Eon") and Sandoz, Inc.'s ("Sandoz," or, together with Eon, "Defendants") Motion to Dismiss Plaintiffs' Second Amended Complaint. ECF No. 40. Plaintiffs oppose Defendants' motion. ECF No. 44. For the reasons explained below, Defendants' motion is **GRANTED**.

I. BACKGROUND[1]

This action arises out of Defendants' allegedly wrongful manufacturing, marketing, and sale of a generic prescription drug. See generally SAC.

Defendants are pharmaceutical companies that manufacture, promote, and sell Amiodarone, a generic version of the brand name anti-arrhythmic heart medication Cordarone. See id. ¶¶ 192-93, 206. Cordarone is manufactured by non-party Wyeth Pharmaceuticals. Id. ¶ 206. Plaintiffs are 277 individuals collectively residing in over thirty different states who either ingested Amiodarone or are the family members of individuals who died from or were injured by Amiodarone after being diagnosed with atrial fibrillation. See id. ¶¶ 1-191; see also ECF No. 39.1.

In 1985, Wyeth received a "special 'needs' approval" from the Food and Drug Administration ("FDA") to market Cordarone "only as a drug of last resort for patients suffering

[1] All facts are drawn from the Second Amended Complaint ("SAC"). ECF No. 39.

from documented, recurrent, life-threatening, ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies." SAC ¶¶ 206-07. However, the drug was never approved for the treatment of atrial fibrillation. Id. ¶ 207.

To obtain approval for manufacturing a generic pharmaceutical, generic drug manufacturers like Defendants need not repeat the clinical trial process required of brand-name manufacturers. Id. ¶ 203. Instead, the Hatch-Waxman Amendments to the federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., permit generic manufacturers to submit an Abbreviated New Drug Application ("ANDA") to the FDA after the FDA has approved the generic drug's brand-name equivalent. Id. The FDA approved Defendants' ANDA for Amiodarone in 1998.[2]

In the SAC, Plaintiffs allege that Wyeth aggressively and successfully marketed Cordarone for inappropriate "off-label" use as a "first-line anti-arrhythmic therapy." Id. ¶ 208 (internal quotation marks omitted). According to Plaintiffs, Wyeth's promotional campaigns often focused on the use of Amiodarone for treatment of atrial fibrillation, even though the FDA never approved the drug for such general use, and failed to warn physicians about the dangers of prescribing Amiodarone for patients with atrial fibrillation. Id. Plaintiffs assert that as a result of Wyeth's marketing efforts, physicians began prescribing Amiodarone as a first-line therapy for atrial fibrillation. Id. They further allege that "Defendants took advantage of Wyeth's marketing plan positioning Amiodarone as a 'first line anti-arrhythmic' . . . and directly benefited from the decades of marketing of the drug for 'off-label' uses by Wyeth." Id. ¶ 209.

[2] The Court takes judicial notice of Defendants' publicly available ANDA approved by the FDA on December 23, 1998. See FDA, ANDA 75-315 (Dec. 23, 1998), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/75315ltr.pdf (last visited Nov. 9, 2021).

In addition, Plaintiffs contend that Defendants: (1) failed to comply with an FDA regulation requiring manufacturers of Amiodarone to provide or make available for distribution a Medication Guide that details for patients the drug's medical uses and health risks; and (2) failed to report certain adverse medical events, injuries, and deaths to the FDA, healthcare professionals, and consumers. See id. ¶¶ 217, 219, 260-62.

Plaintiffs commenced this action against Defendants on January 13, 2020. ECF No. 1. On November 17, 2020, Plaintiffs filed a First Amended Complaint, which Defendants moved to dismiss. ECF Nos. 9, 32, 33. By Order dated December 30, 2020, the Court found that Plaintiffs' claims in the First Amended Complaint were "based vaguely on federal regulations, 'state law,' . . . and 'New Jersey state law,'" and granted them additional time to file an amended pleading that "carefully address[es] the applicable state law and theories of liability under state law as to each plaintiff." ECF No. 35 at 2, 4. Plaintiffs filed the SAC on February 1, 2021, asserting the following causes of action: (1) strict products liability – failure to warn under the New Jersey Products Liability Act ("NJPLA"), N.J. Stat. Ann. §§ 2A:58C-2 et seq. ("Count I"); (2) in the alternative to Count I, statutory and common law negligence – failure to warn under the laws of Plaintiffs' home states ("Count II"); (3) wrongful death ("Count III"); and (4) violation of consumer protection and deceptive trade practices laws ("Count IV"). SAC ¶¶ 291-335. Thereafter, Defendants moved to dismiss the SAC, which Plaintiffs opposed. ECF Nos. 40, 44.

II. LEGAL STANDARD

In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true all of the facts in the complaint and draws all reasonable inferences in favor of the plaintiff. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008). Dismissal is inappropriate simply because "it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits."

Id. The facts alleged, however, must be "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). The allegations in the complaint "must be enough to raise a right to relief above the speculative level." Id. at 555. Accordingly, a complaint will survive a motion to dismiss if it provides a sufficient factual basis such that it states a facially plausible claim for relief. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

III. ANALYSIS

A. Federal Preemption

Defendants argue that the SAC must be dismissed in its entirety because all of Plaintiffs' claims are preempted by federal law. ECF No. 40.1. The Court agrees.

The Court begins its analysis with a brief summary of federal preemption. "The doctrine of preemption has constitutional roots in the Supremacy Clause, which provides that 'the Laws of the United States ... shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" Sikkelee v. Precision Airmotive Corp., 907 F.3d 701, 709 (3d Cir. 2018) (quoting U.S. Const. art. VI, cl. 2.). As such, "Congress . . . has the power to preempt state law." Id. At 709. Generally, federal preemption arises under three circumstances: "(1) when a federal statute includes 'an express provision for preemption'; (2) '[w]hen Congress intends federal law to "occupy the field"' in an area of law; and (3) when a state and federal statute are in conflict." In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II), 751 F.3d 150, 158-59 (3d Cir. 2014) (quoting Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000)).

With respect to conflict preemption, courts have recognized "two types": "(1) impossibility preemption, where compliance with both federal and state duties is impossible; and (2) obstacle preemption, where compliance with both laws is possible, but state law poses an obstacle to the

full achievement of federal purposes." Sikkelee, 907 F.3d at 709. "'Impossibility' preemption issues arise with some regularity in litigation asserting state-law tort claims against prescription-drug manufacturers," Jankowski v. Zydus Pharms. USA, Inc., No. 20-2458, 2021 WL 2190913, at *3 (D.N.J. May 28, 2021). Unlike brand-name drug manufacturers, however, "a generic manufacturer has an ongoing duty of sameness [under federal law]—the generic's ingredients, safety, efficacy, and warning labels must remain identical to its branded equivalent." Frei v. Taro Pharms. U.S.A., Inc., 443 F. Supp. 3d 456, 466 (S.D.N.Y. 2020), aff'd sub nom. Frei v. Taro Pharm. U.S.A., Inc., 844 F. App'x 444 (2d Cir. 2021) (quoting PLIVA, Inc. v. Mensing, 564 U.S. 604, 613). The Supreme Court has thus held that state law failure to warn claims "could not go forward against generic drug manufacturers, as it is impossible for them to comply simultaneously with their state duty to adequately warn and their federal duty of sameness." Id. at 466 (internal citation and quotation marks omitted). For impossibility preemption, "'[t]he question . . . is whether the private party could independently do under federal law what state law requires of it.'" Sikkelee, 907 F.3d at 709 (quoting Mensing, 564 U.S. at 620).

Finally, "state law claims are impliedly preempted" where they "'exist solely by virtue of the FDCA ... requirements.'" Frei, 443 F. Supp. 3d at 468 (quoting Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. at 352). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . ." Buckman Co., 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).

With these principles in mind, the Court now turns to the merits of the parties' arguments. As Defendants appear to concede, the FDCA does not contain an express preemption provision that applies to prescription drugs. Jankowski, 2021 WL 2190913, at *2 (citing Riegel v. Medtronic, Inc., 552 U.S. 312, 327 (2008)). Defendants instead contend that Plaintiffs' claims are

impliedly preempted by federal law. See ECF No. 40.1 at 8 n.4, 17-24. The parties generally divide the SAC's allegations into three categories, all of which appear to underpin the Count I NJPLA, Count II negligence, and Count IV consumer fraud[3] claims: (1) Defendants' alleged failure to provide Medication Guides; (2) Defendants' alleged off-label promotion of Amiodarone; and (3) Defendants' alleged failure to report adverse events to the FDA.[4] See ECF No. 40.1 at 16-24; ECF No. 44 at 18-24; ECF No. 48 at 10-15. The Court will address preemption of each category of allegations in turn.

B. Failure to Provide Medication Guides

Plaintiffs assert that Defendants' Amiodarone failed to contain adequate warnings because "it did not have a medication guide and Defendant[s] did not provide all FDA warnings to Plaintiffs' doctors" and patients. SAC ¶ 307; see also ECF No. 44 at 17-18. Defendants argue that these claims are preempted because they are based on duties imposed by federal, rather than state, law. ECF No. 40.1 at 22. The Court agrees with Defendants.

The FDA regulation titled "Distributing and dispensing a Medication Guide" states, in relevant part, that:

[3] The Court notes that to the extent Count II asserts negligence claims under New Jersey law and Count IV asserts consumer fraud claims under the New Jersey Consumer Fraud Act ("NJCFA"), N.J.S.A. 56:8-1 et seq., based on Amiodarone's warnings, those claims as currently pled are subsumed by the NJPLA and must be dismissed. See Sun Chem. Corp. v. Fike Corp., 243 N.J. 319, 336 (2020) ("If a claim is premised upon a product's manufacturing, warning, or design defect, that claim must be brought under the PLA with damages limited to those available under that statute; CFA claims for the same conduct are precluded.")

[4] Defendants also argue that the SAC alleges that Defendants' Amiodarone labeling should have contained different or additional warnings. ECF No. 40.1 at 17. In their opposition, however, Plaintiffs maintain that their claims are not based on the content of Defendants' labels. ECF No. 44 at 17. Rather, they contend that Defendants' warnings were inadequate "only because . . . Defendants did not provide all FDA warnings to patients and their doctors." Id. (emphasis in original). To the extent the SAC asserts any state law claim that would have required Defendants to include different information on their labels than required under federal law, that claim is impliedly preempted insofar as it would obligate Defendants to violate the federal duty of sameness. See In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II), 751 F.3d at 163 ("[U]nder the FDCA a generic [drug manufacturer] may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability.") (internal citation and quotation marks omitted).

> (b) Each manufacturer who ships a container of drug product for which a Medication Guide is required . . . is responsible for ensuring that Medication Guides are available for distribution to patients by either:
>
> > (1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or
> >
> > (2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product.

21 C.F.R. § 208.24(b).

The regulation further provides:

> (e) Each authorized dispenser of a prescription drug product for which a Medication Guide is required . . . shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent) . . .

21 C.F.R. § 208.24(e).

Thus, "the regulatory text obligates manufacturers to provide medication guides in sufficient numbers, or the means to produce them in sufficient numbers, to distributors, so that such distributors could in turn provide the medication guides to patients." Jankowski, 2021 WL 2190913, at *3; Frei, 443 F. Supp. 3d at 468 (S.D.N.Y. 2020).

The Jankowski and Frei decisions are instructive here. Both cases involved nearly identical failure to warn claims brought against generic manufacturers of Amiodarone. The Jankowski and Frei courts concluded that the claims were impliedly preempted by federal law because "[a]lthough plaintiffs couch their failure to warn claims in traditional state tort law, it is clear the existence of the FDA's medication guide regulation is the gravamen of these claims. There is no question [the defendant's] amiodarone medication guide is a critical element in this case." Frei, 443 F. Supp.

3d at 468 (internal citation and quotation marks omitted); see also Jankowski, 2021 WL 2190913, at *4. The courts emphasized that the plaintiffs had failed to identify any state law analogue to the FDCA's Medication Guide requirement. Frei, 443 F. Supp. 3d at 468; Jankowski, 2021 WL 2190913, at *4.

The Court reaches the same conclusion here. While Plaintiffs argue that "federal law does not solely supply the elements of [their] claims," ECF No. 44 at 19, this contention does not square with the allegations in the SAC. The SAC does not identify any state law requiring generic manufacturers to provide a Medication Guide; to the contrary, it repeatedly references the FDA regulations on Medication Guides. See, e.g., SAC ¶ 226 (alleging that "Defendants are . . . responsible for the consumer receiving the FDA-approved Medication Guide with each Amiodarone prescription," but failed to do so); id. ¶ 227 ("Because their pharmacists were not provided a Medication Guide in sufficient quantity to give directly to them as required by FDA regulations, Plaintiffs did not know 'the medicine stays in your body for months after treatment is stopped'"); id. ¶ 283 ("At all material times, Defendants engaged in a continuing course of misstatements, illegal conduct, concealment and/or non-disclosure of material facts," including failing "to ensure a Medication Guide in compliance with FDA regulations is received by a Plaintiff's dispensing pharmacy and ultimately by each Plaintiff"). Quite clearly, "[a]lthough plaintiffs couch their failure to warn claims in traditional state tort law, . . . the existence of the FDA's medication guide regulation is the gravamen of these claims." Frei, 443 F. Supp. 3d at 468. Because state law claims that "'exist solely by virtue of the FDCA ... requirements'" are impliedly

preempted by federal law, Plaintiffs' claims based on Defendants' alleged failure to provide Medication Guides must be dismissed. Id. (quoting Buckman Co., 531 U.S. at 352).[5]

C. Off-Label Promotion

Plaintiffs contend that Defendants engaged in consumer fraud by "promoti[ng] . . . Amiodarone for dangerous off-label uses contrary to the limited approval given by the FDA." ECF No. 44 at 23. Defendants counter that any such consumer fraud claims are impliedly preempted by federal law. ECF No. 40 at 20. The Court agrees with Defendants.

As in both Jankowski and Frei, Plaintiffs' off-label promotion claims here appear to be based on Defendants' allegedly taking advantage of Wyeth's efforts to market Amiodarone as a first-line anti-arrhythmic medication and failure to correct information in third-party reference sources relied on by physicians about the use of Amiodarone for the treatment of atrial fibrillation. See SAC ¶¶ 209, 216, 298; Jankowski, 2021 WL 2190913, at *5; Frei, 443 F. Supp. 3d at 468. Plaintiffs assert that Defendants "were under a duty to correct these materials as a form of labelling." SAC ¶ 298.

Plaintiffs' claims are impliedly preempted by federal law for two reasons. First, to the extent the SAC alleges that Defendants were required to alter the content of the Amiodarone label and thereby violate the federal duty of sameness, those claims are subject to Mensing preemption. As explained above, in Mensing, the Supreme Court found that "state failure-to-warn claims were pre-empted by the FDCA because it was impossible for [generic] drug manufacturers . . . to comply with both the state-law duty to label their products in a way that rendered them reasonably safe and the federal-law duty not to change their drugs' labels." Mut. Pharm. Co. v. Bartlett, 570 U.S.

[5] Because the Court finds that federal law preempts the claims based on Defendants' alleged failure to provide Medication Guides, it need not reach the issue of whether such claims are barred by the learned intermediary doctrine, as well.

472, 488 (2013) (citing Mensing, 564 U.S. at 616-20). Because the SAC alleges that the information in the third-party sources constituted "labelling," Plaintiffs' off-label promotion claims are impliedly preempted under Mensing and must be dismissed.

In addition, as Defendants correctly note, the off-label promotion claims are also preempted under Buckman because they are premised on obligations imposed by federal law that private litigants may not enforce. ECF No. 40 at 20. Specifically, in the SAC, Plaintiffs cite to FDCA provisions that make it "unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug." SAC ¶ 208 & n.9 (citing 21 U.S.C. §§ 331(d), 352(f), 355). They do not identify any applicable state law that parallels the FDCA's requirements. See ECF No. 44 at 23-24. Thus, because Plaintiffs' off-label promotion claims, as currently pled, rest solely on federal law, they are impliedly preempted. See Perdue v. Wyeth Pharms., Inc., 209 F. Supp. 3d 847, 852 (E.D.N.C. 2016) (finding off-label promotion claims impliedly preempted under Buckman because "[t]he restrictions and guidelines placed upon pharmaceutical companies for off-label promotion are entirely dependent upon the statutory and regulatory scheme created by the FDCA"); Frei, 443 F. Supp. 3d at 468-69 (dismissing off-label use and promotion claims "because the duties [plaintiffs allege Taro] breached regarding off-label promotion exist solely under the FDCA") (internal citation and quotation marks omitted).

D. Failure to Report Adverse Events to the FDA

Finally, Plaintiffs contend that their claims premised on Defendants' alleged failure to report all adverse events to the FDA are not preempted because they are cognizable under both federal and state law. ECF No. 44 at 24. The Court disagrees.

As an initial matter, the Court notes that Plaintiffs assert that their failure to report claims are governed by New Jersey law. See id. at 45. While certain jurisdictions recognize that "'a

manufacturer's failure to report adverse events to the FDA can form the basis of a parallel claim that survives preemption' . . . New Jersey is a jurisdiction that 'declin[es] to recognize a separate state law duty to warn the FDA.'" Jankowski, 2021 WL 2190913, at *5 (quoting In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig., No. 19-2921, 2021 WL 1050910, at *11 (D.N.J. Mar. 19, 2021)). Consequently, Plaintiffs cannot maintain their failure to report adverse events claims under New Jersey law.[6]

Furthermore, the Court notes that the SAC does not adequately allege that Defendants failed to report adverse events to the FDA. Plaintiffs generally assert that "[t]here are millions o[f] persons who are diagnosed with [atrial fibrillation] annually" and "Amiodarone over the years has become the number one prescribed drug for the treatment of" this condition. SAC ¶ 258. As a result, Plaintiffs allege, "[b]ased on the percentages of persons diagnosed just with pulmonary toxicity, there would be tens of thousands or adverse event reports submitted each year," but "that does not appear to be even close to the number of these reports submitted to the FDA in connection with Amiodarone." Id. They assert that adverse event reports "increased significantly in the last few years . . . correlating to the litigation surrounding Amiodarone which began in 2015." Id. ¶ 263. According to the SAC, this alleged increase "indicates . . . underreporting of [adverse events] in the years before the Amiodarone litigation." Id. Plaintiffs do not sufficiently identify, however, any actual adverse event that Defendants did not report to the FDA. Accordingly, Plaintiffs' failure to report claims are dismissed. See Jankowski, 2021 WL 2190913, at *5 ("Because Plaintiffs fail to allege actual adverse events that [Zydus] did not report to the FDA, the

[6] While Plaintiffs rely on Freed v. St. Jude Med., Inc., 364 F. Supp. 3d 343 (D. Del. 2019) to argue that the failure to report claims are not subject to Buckman preemption, ECF No. 44 at 24, their reliance is misplaced. Unlike Plaintiffs' claims here, which they contend are governed by New Jersey law, Freed involved failure to report claims brought under Delaware law. Freed, 364 F. Supp. 3d at 360.

Court finds that Plaintiffs' conclusory and speculative allegations are insufficient to state a parallel failure to warn claim.") (internal citation and quotation marks omitted).[7]

IV. CONCLUSION

For the reasons set forth above, the SAC is dismissed without prejudice.

Accordingly, it is on this 9th day of November, 2021,

ORDERED that Defendants' motion to dismiss, ECF No. 40, is **GRANTED**; and it is further

ORDERED that to the extent Plaintiffs can cure the defects identified herein, they may file an amended pleading within thirty (30) days of the date of this Order; and it is further

ORDERED that if either party concludes that New Jersey law does not apply to any of the claims in Plaintiffs' amended pleading, they shall address the effect of that conclusion in any subsequent motion to dismiss, including whether this action should be severed and/or transferred to another district.[8]

/s Madeline Cox Arleo
MADELINE COX ARLEO
UNITED STATES DISTRICT JUDGE

[7] To the extent Plaintiffs alternatively plead their failure to report claims under the various laws of their home states, Plaintiffs have failed to comply with the Court's prior directive to "carefully address the applicable state law and theories of liability under state law as to each plaintiff." ECF No. 35 at 4. Although Plaintiffs insist they complied with the Court's instructions by including a citation to In re Accutane Litig., 235 N.J. 229 (2018) in the SAC, ECF No. 44 at 8, a cursory review of that decision reveals that Plaintiffs did not conduct the fulsome choice-of-law analysis contemplated by the Court's prior Order. Indeed, as the In re Accutane Litig. court explained, New Jersey has "adopted the Restatement[(Second) Conflict of Laws] most-significant-relationship test set forth in sections 146, 145, and 6 as the paradigm for deciding which state's substantive law applies in personal injury cases involving more than one state." 235 N.J. at 257. Neither the SAC nor Plaintiffs' opposition brief addresses the Restatement's most-significant-relationship test, which requires the Court to, inter alia, evaluate each state's contacts by considering "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicil[e], residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered." Id. at 260. The Court will grant Plaintiffs one final opportunity to replead and brief the choice-of-law issues in accordance with all relevant authority.

[8] Plaintiffs concede that "their wrongful death claims are premised on their other claims." ECF No. 44 at 37 n.6. Because Plaintiffs' other claims are dismissed, the Court must dismiss their derivative wrongful death claims, as well. The Court need not reach the parties' contentions regarding whether certain Plaintiffs' claims are time-barred.