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United States District Court, D. New Jersey.

ZAMFIROVA, et al., Plaintiffs,
v.
AMAG PHARMACEUTICALS, INC., Defendant,

Civil Action No. 20-cv-00152
|
Filed 05/25/2021

OPINION

John Michael Vazquez, U.S.D.J.

***1** This putative class action arises out of the Defendant's marketing and sale of the prescription drug Makena to Plaintiffs. This matter comes before the Court by way of Defendant's motion to dismiss Plaintiffs' Consolidated Amended Class Action Complaint, D.E. 15 ("FAC"). The Court reviewed the parties' submissions[1] in support and in opposition and decided the motion without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the reasons stated below, Defendant's motion is granted.

I. BACKGROUND

Defendant AMAG Pharmaceuticals, Inc. ("AMAG") is a pharmaceutical company that currently holds the rights to market and sell the prescription drug Makena. FAC ¶ 14. AMAG and previous companies have marketed and sold Makena to prevent premature births. *Id*. ¶ 1. Plaintiffs are residents of California, New York, New Jersey, Kansas, Missouri, and Wisconsin who were "prescribed, injected with, and purchased Makena." *Id*. ¶¶ 2-13. Plaintiffs claim that AMAG misrepresented the effectiveness of Makena. *Id*.

The active chemical ingredient in Makena is hydroxyprogesterone caproate, which has been on the market since 1956. *Id*. ¶ 18. Plaintiffs allege that hydroxyprogesterone caproate was initially developed in the early 1950s. *Id*. ¶ 19. In 1956, a company named "Squib" acquired the license to the patent and marketed it under the brand name Delalutin to treat abnormal bleeding in patients with uterine cancer and later to treat pregnant women who had tumorous ovaries removed. *Id*. ¶ 19-20. In the 1990s, Delalutin was used to treat imminent premature birth threat during pregnancy; however, in 1995, Bristol Myers Squib voluntarily withdrew the drug from the market. *Id*. ¶ 19-22.

A company called Hologic then developed and obtained FDA approval for Makena.[2] *Id*. ¶ 23. On February 3, 2011, the FDA approved the New Drug Application ("NDA") that Hologic filed, seeking "accelerated approval" for Makena. *Id*. ¶ 29. According to Plaintiffs, "the data used to support Makena's fast-track application and subsequent approval ... was insufficient to assess Makena's efficacy." *Id*. ¶ 30. Plaintiffs claim that the FDA "relied heavily on a single clinical trial published in 2003 by the National Institute of Child Health and Human Development." *Id*. ¶ 31.

Plaintiffs allege that a statistical review and evaluation by the FDA in 2010 found that reliance on the 2003 study was insufficient to establish the efficacy of Makena in preventing preterm births. *Id*. Plaintiffs indicate that the FDA's review found that the 2003 trial (1) "failed to identify the optimal time to start taking Makena"; (2) "one study center accounted for nearly half of the subjects, calling into question the effectiveness of the study's randomizations"; and (3) "women treated with Makena experienced fetal and neonatal deaths earlier than women who were taking a placebo." *Id*. ¶ 32. Nonetheless, "the FDA approved [Makena] on a fast-track basis, allowing the drug to hit the U.S. market." *Id*. ¶ 34.

***2** Plaintiffs assert that the previous owners of Makena have overcharged for the drug and have also aggressively attacked the efficacy of the generic form of Makena, "17P." *Id*. ¶¶ 35-57. Plaintiffs note that "a 2013 study appeared to find that [Makena] might reduce the risk of preterm births in at-risk mothers." *Id*. ¶ 26. Through a series of transactions, AMAG acquired the exclusive rights to market and sell Makena. *Id*. ¶¶ 23-27. Plaintiffs add that AMAG followed its predecessors in overcharging for Makena. *Id*. ¶ 41.

The fast-tracked approval of Makena was conditioned on a follow-up clinical trial to confirm the drug's efficacy. *Id*. ¶ 58. On March 8, 2019, AMAG revealed the results of that FDA mandated follow-up trial, known as the PROLONG Study. *Id*. ¶ 59. The PROLONG Study revealed "no statistically significant differences concerning miscarriage and stillbirths ... between Makena and the placebo treatment." *Id*. ¶ 61. Specifically, "11% of the women in the study

who took Makena delivered their babies at 35 weeks or earlier, whereas 11.5% of women who took the placebo delivered their babies at 35 weeks or earlier." *Id*. ¶ 61. After the PROLONG Study results were revealed, the FDA's Bone, Reproductive and Urologic Drugs Advisor Committee recommended that Makena be withdrawn from the market. *Id*. ¶ 63. Plaintiffs allege that "[o]n information and belief, both because of the original problems with the Meiss study, and because the incoming data for the PROLONG trial were showing Makena was ineffective, AMAG knew far earlier than finalization of the PROLONG study that Makena was ineffective." *Id*. ¶ 64.

Plaintiffs continue that, after the PROLONG Study, the health insurance industry signaled that it would not pay claims for Makena treatment due to inefficacy. *Id*. ¶ 65. Plaintiffs assert that AMAG has responded with claims that removing Makena from the market would exacerbate inequitable health outcomes in healthcare. *Id*. ¶ 69. AMAG has not yet removed Makena from the market. *Id*. ¶ 70.

Plaintiffs claim that certain statements (discussed below) by AMAG concerning Makena violate the consumer protection laws of several states. Plaintiffs general theory is that "AMAG's statements that Makena was effective in reducing preterm births constitute unconscionable commercial conduct." *Id*. ¶¶ 87, 94, 105, 115, 122, 131, 140. Plaintiffs contend that but for misleading statements that Makena was effective, they would not have purchased or been injected with Makena. *Id*. ¶ 76.

II. PROCEDURAL HISTORY

Plaintiffs filed their initial Complaint on January 3, 2020. D.E. 1. On April 2, 2020, Plaintiffs filed their FAC. D.E. 15. The FAC is comprised of the following counts: (1) violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-2 ("NJCFA") (Count One); (2) violation of the California Bus. & Prof. Code § 17200 (Count Two); (3) violation of the California Consumer Legal Remedies Act, Cal. Civ. Code § 1770 *et seq*. ("CCLRA") (Count Three); (4) violation of the Kansas Consumer Protection Act, Kan. Stat. § 50-623, *et seq.*, ("KCPA") (Count Four); (5) violation of the Missouri Merchandising Practices Act, RSMo § 407.010, *et seq.*, ("MMPA") (Count Five); (6) violation of New York General Business Law Section 349(a) ("NYGBL") (Count Six); (7) violation of the Wisconsin Deceptive Trade Practices Act ("WDTPA") (Count Seven); and (8) unjust enrichment (Count Eight). The current motion followed.

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(6) of the Federal Rules of Civil Procedure permits a defendant to move to dismiss a count for "failure to state a claim upon which relief can be granted[.]" To withstand a motion to dismiss under Rule 12(b)(6), a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint is plausible on its face when there is enough factual content "that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although the plausibility standard "does not impose a probability requirement, it does require a pleading to show more than a sheer possibility that a defendant has acted unlawfully." *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016) (internal quotation marks and citations omitted). As a result, a plaintiff must "allege sufficient facts to raise a reasonable expectation that discovery will uncover proof of [his] claims." *Id*. at 789.

***3** In evaluating the sufficiency of a complaint, a district court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). A court, however, is "not compelled to accept unwarranted inferences, unsupported conclusions or legal conclusions disguised as factual allegations." *Baraka v. McGreevey*, 481 F.3d 187, 211 (3d Cir. 2007). If, after viewing the allegations in the complaint most favorable to the plaintiff, it appears that no relief could be granted under any set of facts consistent with the allegations, a court may dismiss the complaint for failure to state a claim. *DeFazio v. Leading Edge Recovery Sols.*, 2010 WL 5146765, at *1 (D.N.J. Dec. 13, 2010).

For allegations sounding in fraud, Rule 9(b) imposes a heightened pleading standard. Specifically, a party alleging fraud "must state with particularity the circumstances constituting fraud or mistake," but "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). A plaintiff must plead fraud with sufficient particularity such that he puts the defendant on notice of the "precise misconduct with which [he is] charged." *Lum v. Bank of Am.*, 361 F.3d 217, 223-24 (3d Cir. 2004), *abrogated in part on other grounds by Twombly*, 550 U.S. at 557. "To satisfy this standard, the plaintiff must plead or allege the date, time, and place of the alleged fraud or otherwise inject precision or some measure

of substantiation into a fraud allegation." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007).

IV. ANALYSIS

A. AMAG's Motion to Dismiss Plaintiffs' Consumer Fraud Claims as Preempted

AMAG first moves to dismiss all consumer fraud claims, Counts One through Seven, based on preemption. Br. at 11. AMAG argues that Plaintiffs' claims concerning AMAG's marketing materials constitute an attack on Makena's label itself. *See* Br. at 14 ("Courts have held that claims challenging marketing materials that mirror FDA-approved labeling are preempted because such a finding 'would be fundamentally equivalent to finding that FDA's approved labeling was false or deceptive.' " (citing *Williams v. Bayer Corp.*, 541 S.W.3d 594, 602-03 (Mo. Ct. App. 2017)).

In *Williams*, a Missouri appellate court rejected a plaintiff's argument that the court should not conduct a preemption analysis because the misstatements complained of "were made on a website promoting the product, something that the FDA neither regulates nor reviews." *Williams*, 541 S.W.3d at 602-03. The court found that the alleged misstatements "were nearly identical" to the FDA approved labeling for the device at issue and concluded that "a finding that the statements made on the [ ] website were false or deceptive ... would be fundamentally equivalent to finding that the FDA's approved labeling was false or deceptive." *Id*. The court therefore applied a preemption analysis. *Id*. Defendants also rely on *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007), which reached a similar conclusion. *See id*. ("[T]he alleged advertisements derive from and largely comport with, the approved label. For this reason, the plaintiff's efforts to hold Pfizer liable for the advertisements conflicts with the FDA's jurisdiction over drug labeling."); *see also English v. Bayer Corp.*, 468 F. Supp. 3d 573, 581 (W.D.N.Y. 2020) (applying preemption analysis to Plaintiffs' misrepresentation and breach of express warranty claims because "[a]lthough plaintiffs point to numerous differences in verbiage between the FDA-approved labeling of Essure and defendants' own representations ... plaintiffs have not identified any statements by defendants that substantively stray beyond those approved by the FDA.").

***4** In opposition, Plaintiffs focus on the substance of Defendant's preemption argument. However, Plaintiffs' briefly claim that "AMAG points to no evidence that the FDA approved its marketing.... AMAG repeatedly asks the Court to speculate that FDA approval of the 2011 label somehow confers approval of its subsequent marketing efforts." Opp. at 7. Yet, Plaintiffs do not cite any authority in support nor do they attempt to distinguish Defendant's cases. Importantly, it does appear that Plaintiffs are seeking to hold AMAG liable for statements which derive from and are consistent with Makena's label.

Plaintiffs claim that the following statements by AMAG concerning Makena violate the consumer protection laws of California, New York, New Jersey, Kansas, Missouri, and Wisconsin: (1) "Makena helps you get closer to term"; (2) "Makena ... is a hormone medicine (progestin) prescribed to lower the risk of having another preterm baby in women who are pregnant with one baby, and who've unexpectedly delivered one baby too early (before 37 weeks) in the past"; and (3) "Makena gives moms an extra layer of support"; and, (4) "Makena ... helps give bab[ies] more time to develop." *See e.g., id*. ¶ 88. In addition, Plaintiffs seek to recover for the following "marketing testimonials" by Makena users: (1) "Receiving the weekly injections of Makena is giving me the peace of mind knowing that I'm doing everything I can to help prolong this pregnancy"; and (2) "Looking back, Makena gave me hope that I had a better change of delivering Olivia to full term." *Id*. As noted, Plaintiffs overarching claim is that "AMAG's statements that Makena was effective in reducing preterm births constitute unconscionable commercial conduct." *Id*. ¶¶ 87, 94, 105, 115, 122, 131, 140.

The statements appear to be consistent with the FDA's approved label for Makena. In relevant part, the label provides that "Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth." D.E. 25-2 at 6.[3] Plaintiffs do not provide an analysis as to how the challenged misstatements exceed the bounds of the label in any significant way. To the contrary, Plaintiffs' FAC generally describes AMAG's problematic representation as follows: "that Makena was effective in reducing preterm births." *Id*. ¶¶ 87, 94, 105, 115, 122, 131, 140. In their opposition, Plaintiffs claim that Makena's label itself "is a thicket of misleading half-disclosures and omissions" that is "unquestionably misleading." Opp. at 3. In other words, "as the complaint reads, [AMAG] would need to change [Makena's] label in order to avoid liability under state law." *See In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779

F.3d 34, 40 (1st Cir. 2015). For its part, Defendant provided a detailed analysis comparing the alleged misstatements against the label, and Plaintiffs failed to point to any meaningful differences. *See* Opp. at 4-7. Accordingly, the Court will engage in a preemption analysis as to Plaintiffs' claims.

***5** The Supremacy Clause of the Constitution provides that federal law "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. States are free to legislate as they see fit, "subject only to limitations imposed by the Supremacy Clause." *Tafflin v. Levitt*, 492 U.S. 455, 458 (1990). Federal law "preempts" state law in three situations: "(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 statue are in conflict." *In re Foxomax (Alendronate Sodium) Products Liability Litigation (No. II)*, 751 F.3d 150, 158-159 (3rd Cir. 2014) (internal citations omitted). The third scenario, "conflict preemption," includes two types: impossibility preemption and obstacle preemption. *Id*. at 159. Here, Defendants argue conflict preemption under the impossibility theory.

The crux of the impossibility analysis is whether it is "impossible for [a private party] to comply with both federal and state requirements." *Crockett v. Luitpold Pharms., Inc.*, No. CV 19-276, 2020 WL 433367, at *6 (E.D. Pa. Jan. 28, 2020) (quoting *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)). "[I]mpossibility preemption is a 'demanding defense,' and there is a presumption against it." *Id*. (quoting *Wyeth*, 555 U.S. at 573). The applicability of preemption is "for a judge, to decide, not a jury." *Merck Sharp & Dohme Corp. v. Albrecht*, -- U.S. --, 139 S. Ct. 1668, 1672 (2019). "[W]hen impossibility preemption presents a purely legal issue, the Court may decide it on a Rule 12 motion." *Crockett*, No. CV 19-276, 2020 WL 433367, at *6 (citing *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623–24 (2011)). "However, dismissal under Rule 12(b)(6) is appropriate only when 'preemption is manifest in the complaint itself.' " *Id*. A complaint may be dismissed at the Rule 12 stage if 'the plaintiff's own allegations show that a defense exists that legally defeats the claim for relief.' " *Id*.

"The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Wyeth*, 555 U.S. at 568 (citing 21 U.S.C. § 355; 21 C.F.R. § 314.105). In *Wyeth*, the Supreme Court held that state law claims requiring the alteration of a drug's label are not preempted as a matter of course. The Court explained that although "[g]enerally speaking, a manufacturer may only change a drug label *after* the FDA approves a supplement application ... an FDA regulation [ ] permits a manufacture to make certain changes to its label *before* receiving the agency's approval." *Id*. (emphases added). This "Changes Being Effected" ("CBE") exception, *see* 21 C.F.R. § 314.70(c)(6)(iii)(A)), among other things, allows a manufacturer to "add or strengthen a contraindication, warning, [or] precaution" without pre-approval from the FDA. *Id*. The CBE exception permits labelling changes to reflect "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii). The Code of Federal Regulations defines "newly acquired information" as follows:

> [D]ata, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3.

"Because the CBE regulation permits drug manufacturers to change warning labels prior to FDA approval, drug manufacturers ordinarily will not be able to show an actual conflict between state and federal law that would make it impossible to comply with both." *Javens v. GE Healthcare Inc.*, No. CV 18-1030-RGA-SRF, 2020 WL 2783581, at *3 (D. Del. May 29, 2020), *report and recommendation adopted*, 2020 WL 7051642 (D. Del. June 18, 2020) (citing *Merck Sharp*, 139 S. Ct. at 1679). Thus, a state law claim alleging deficiencies in a brand manufacturer's drug's label, like those at issue here, "may survive a preemption challenge if the complaint alleges that new information became available to the drug manufacture after the FDA's initial approval" such that the manufacturer could have availed itself of the CBE exception. *Id*. However, "even though a drug manufacturer has the responsibility under state consumer-protection laws to accurately label a drug and may change the label pursuant to the CBE process prior to receiving approval from the FDA," the FDA may nevertheless reject the label change if it considers it to be mislabeled under federal law. *In re Avandia Mktg., Sales & Prod. Liab. Litig.*, 945 F.3d 749, 758 (3d Cir. 2019). Thus, the "FDCA does not preempt state-law consumer-protection claims regarding the labelling of a drug 'absent clear evidence that the FDA would not have approved a change to the drug's label." *Id*. Clear evidence is evidence that "the drug manufacturer fully informed the FDA of the

justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Id*. (quoting *Merck Sharp & Dohme Corp.*, 139 S. Ct. at 1672).

***6** Defendant first argues that Plaintiffs are making a "never-start-selling" claim that was rejected in *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013). But that case, unlike this one, involved a generic manufacturer. Generic manufacturers are "prohibited from making *any* unilateral changes to a drug's label." *Bartlett*, 570 U.S. at 477. In *Bartlett*, the generic manufacturer could not comply with the duties imposed by New Hampshire's law because federal law forbade it from redesigning its drug and from altering its drug's label in a manner "required to avoid liability under New Hampshire law." *Id*. at 486. As a result, the First Circuit found no impossibility preemption because it reasoned that the generic manufacturer "could escape the impossibility of complying with both its federal-and state-law duties by choosing not to make [the drug] at all." *Id*. at 488 (internal quotation marks and citation omitted). The Supreme Court disagreed, reasoning that the preemption analysis presumes "that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id. Bartlett* is inapposite because AMAG is not a generic manufacturer of Makena. While a brand manufacturer must use the label approved by the FDA, the CBE exception is also available to such a manufacturer, such as AMAG. *Wyeth,* 555 U.S. at 568.

Defendant nonetheless maintains that Plaintiffs are essentially making a claim that it never should have started selling or should stop selling Makena. Specifically, AMAG contends that "Plaintiffs' suggestion that AMAG could simply change its label to state Makena is ineffective is, frankly, absurd. The FDA will not approve – and does not allow manufacturers to sell – prescription drugs that are not effective."[4] Reply at 4, n. 2. AMAG essentially argues that it would have been legally impossible for it to change its label in the manner *it* believes necessary to satisfy Plaintiffs' concerns. Br. at 13; Reply at 8. But the applicable standard is that AMAG must show by "clear evidence" that the FDA would not have approved a change to the drug's label. *Merck*, 139 S. Ct. at 1672. To "show that federal law prohibited [it] from adding a warning that would satisfy state law," AMAG must show (1) it "fully informed the FDA of the justifications for the warning required by state law" by "submitting all material information to the FDA," and (2) the FDA "informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Crockett*, No. CV 19-276, 2020 WL 433367, at *7 (quoting *Merck*, 139 S. Ct. at 1678); *see also Merck*, 139 S. Ct. at 1672 (observing that clear evidence is evidence that demonstrates that "the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." (internal quotation marks omitted)).

Defendant does not show that it tried to change its Makena label pursuant to the CBE Exception. Instead, AMAG's speculates that the FDA would not have approved the label change sought by Plaintiffs. *See* Reply at 4-9. However, "in making a preemption argument, it is not sufficient for the proponent to contend that if it had submitted a new label -- with additional warnings -- to the FDA, the FDA *would have* rejected the warning." *Crockett*, No. CV 19-276, 2020 WL 433367, at *7 (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011)). "The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *Id*. Defendant has not supported its arguments with the necessary evidence.

AMAG next argues that the FAC fails to plausibly allege a defect that it could have remedied through the CBE exception. Defendant explains that, as pled, AMAG could not have altered Makena's label pursuant to the CBE exception prior to the release of the PROLONG study in March 2019. *Id*. at 7, n. 5 (citing *McGrath v. Bayer HealthCare Pharm. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019) (emphasis in original)); *see also id*. at 9. Defendant contends that the only allegations in the FAC that could possibly qualify as "newly acquired information" under 21 C.F.R. § 314.70(c)(6)(iii) are those relating to the PROLONG study, which was released on March 8, 2019.

***7** Several courts have held that dismissal at the pleading stage is appropriate if the complaint fails to present sufficient factual allegations to show that the manufacturer could have unilaterally changed its label in accordance with the CBE exception. *See In re Celexa*, 779 F.3d at 41 ("Our review of the Supreme Court opinions discussed above makes clear that a necessary step in defeating Forest's preemption defense is to establish that the complaint alleges a labeling deficiency that Forest could have corrected using the CBE regulation."); *see also Javens v. GE Healthcare Inc.*, No. CV 18-1030-RGA-SRF, 2020 WL 2783581, at *5 (D. Del. May 29, 2020), *report*

and recommendation adopted, No. CV 18-1030-RGA-SRF, 2020 WL 7051642 (D. Del. June 18, 2020); *McGrath v. Bayer HealthCare Pharms. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019); *Goodell v. Bayer Healthcare Pharms. Inc.*, No. 18-CV-10694-IT, 2019 WL 4771136, at *4 (D. Mass. Sept. 30, 2019).

In *Celexa*, the First Circuit found that the plaintiffs' claims alleging violations of the California Bus. & Prof. Code § 17200, the CCLRA, and California's False Advertising Law were impliedly preempted by federal law. *In re Celexa*, 779 F.3d at 41. There, the plaintiffs alleged that defendant's drug Lexapro's label "overestimated [the drug's] effectiveness." *Id*. at 35. The plaintiffs in *Celexa*, among other things, claimed a change in Lexapro's label was necessary because it had "been shown to be effective in a clinical trial by one point" meaning that "[t]he difference between Lexapro and a placebo is clinically insignificant." *Id*. at 41. The district court dismissed plaintiff's claims due to federal preemption. *Id*. at 39. After analyzing the Supreme Court's decisions in *Wyeth* and *PLIVA, Inc.*, the *Celexa* court concluded that it was "clear that a necessary step in defeating [defendant's] preemption defense is to establish that the complaint alleges a labeling deficiency that [defendant] could have corrected using the CBE regulation." *In re Celexa*, 779 F.3d at 41. After "scrutinize[ing] the complaint," the First Circuit found that the plaintiffs had failed to allege any "newly acquired information," as that term is defined in the CBE exception, that was "unknown prior to label approval." *Id*. at 43. Accordingly, the *Celexa* court found that the plaintiffs' complaint failed to adequately allege that plaintiffs could "independently change its label to read as plaintiffs say it should have in order to comply with California law" and therefore affirmed the dismissal on preemption grounds. *Id*.

Here, AMAG argues that the allegations in the FAC fail to show that AMAG could have availed itself of the CBE exception "until April 2019 at the earliest," meaning that Plaintiffs' claims arising before then are preempted. Reply at 9. Defendant continues that the PROLONG Study is the only potential "newly acquired information" alleged in the FAC that would justify an amendment under the CBE exception. *Id*. As noted, the FAC alleges that "[o]n information and belief, both because of the original problems with the Meiss[5] study, and because the incoming data for the PROLONG trial were showing Makena was ineffective, AMAG knew far earlier than finalization of the PROLONG Study that Makena was ineffective." *Id*. ¶ 64.

***8** The Meis study does not constitute "newly acquired information" because Plaintiffs' FAC acknowledges that the FDA considered both the Meis study and the FDA's Statistical Review and Evaluation of that study *before* approving Makena. S*ee* 21 C.F.R. § 314.3 (defining newly acquired information as "data, analyses, or other information not previously submitted to the Agency[.]" (emphasis added)).

The only allegation that could arguably support a conclusion that AMAG had newly acquired information prior to March 8, 2019 is that, based on information and belief, "AMAG knew far earlier than finalization of the PROLONG Study that Makena was ineffective" because "the incoming data for the PROLONG trial were showing Makena was ineffective[.]" FAC ¶ 64. A plaintiff may plead facts upon information and belief "where it can be shown that the requisite factual information is peculiarly within the defendant's knowledge or control – so long as there are no boilerplate and conclusory allegations and plaintiffs accompany their legal theory with factual allegations that make their theoretically viable claim plausible." *McDermott v. Clondalkin Grp., Inc.*, 649 F. App'x 263, 267-68 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002) (internal punctuation omitted)). Facts pled on information and belief must "set forth the 'specific facts upon which the belief is reasonably based.' " *ICU Medical, Inc. v. RyMed Technologies, Inc.*, 752 F. Supp. 2d 486, 488 (D. Del. 2010) (citing *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

Here, Plaintiffs fail to allege specific facts to support their allegation on information and belief that AMAG knew the results of the PROLONG study "far earlier" than its finalization. Similarly, Plaintiffs fail to indicate how it was possible to ascertain the final results of the "double blinded, placebo-controlled clinical trial," *see* FAC ¶ 61, before all data was collected and analyzed. As a result, Plaintiffs have insufficiently alleged the basis for their "on information and belief" claim.

The FAC alleges the results of the PROLONG study were released on March 8, 2019. FAC ¶ 59. As to Plaintiffs claims arising before that date, Plaintiffs have failed to allege sufficiently that AMAG was aware of "newly acquired information" such that it could have availed itself of the CBE exception before that date. Accordingly, Plaintiffs consumer fraud-based claims that arose before March 8, 2019 are dismissed as preempted. *See Goodell*, No. 18-CV-10694-IT, 2019 WL 4771136, at *4 ("[T]he complaint does not cite

any newly acquired information that arose after the FDA's approval of [the drug's] revised label in 2007 and before Plaintiff was administered [the drug] ... [w]ithout factual allegations that [defendant] had new information in this time period such that it could have amended the label pursuant to the CBE regulation, the complaint is barred as preempted.").

Moreover, the named Plaintiffs have failed to allege the specific date on which they were "prescribed, injected with, and purchased Makena." Instead, each named Plaintiff simply alleges this occurred "during the class period" -- a time period which, although undefined in the FAC, apparently could extend from January 2014 to the present. *See* FAC ¶¶ 2-13; *id*. ¶ 78. Aside from the issues that these vague allegations raise under the applicable pleading standards, the Court cannot determine which, if any, of Plaintiffs' claims survive this Court's finding that claims arising prior to March 8, 2019 are preempted. Because the named Plaintiffs have failed to provide sufficient facts for the Court to determine whether or not their claims are preempted, the Court dismisses all of Plaintiffs' consumer-fraud based claims (Counts One through Seven) without prejudice.[6]

B. Defendant's Motion to Dismiss Plaintiffs' Unjust Enrichment Claim

***9** Plaintiffs' remaining claim is Count Eight, unjust enrichment, which Defendant moves to dismiss on several grounds. Br. at 46-49. Plaintiffs do not appear to respond to Defendant's arguments. *See generally* Opp. Plaintiff's failure to respond could be construed as a waiver. *See Griglak v. CTX Mortg. Co., LLC*, No. 09-5247MLC, 2010 WL 1424023, at *3 (D.N.J. Apr. 8, 2010) ("The failure to respond to a substantive argument to dismiss a count, when a party otherwise files opposition, results in a waiver of that count.").

However, turning to the merits, the unjust enrichment claim is inadequately pled. "To establish a claim for unjust enrichment under New Jersey law, a plaintiff must allege 'both that defendant received a benefit and that retention of that benefit without payment would be unjust.' " *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 505 (D.N.J. 2006) (quoting *VRG Corp. v. GKN Realty Corp.*, 135 N.J. 539, 554 (1994)). However, "[r]estitution for unjust enrichment is an equitable remedy, available only when there is no adequate remedy at law." *Id*. Additionally, "[u]nder New Jersey law, an indirect purchaser cannot succeed on a claim for unjust enrichment." *Spera v. Samsung Elecs. Am., Inc.*, No. 12-05412, 2014 WL 1334256, at *9 (D.N.J. Apr. 2, 2014) (quoting *Weske v. Samsung Elecs. Am., Inc.*, No. 10-4811, 2012 WL 833003, at *7 (D.N.J. Mar. 12, 2012)). "When an individual purchases a consumer product from a third-party store and not the manufacturer, the purchaser has not conferred a benefit directly to the manufacturer such that the manufacturer could be found to have been unjustly enriched." *Id*. (quoting *Weske*, 2012 WL 833003, at *7). Here, Plaintiffs have not alleged they purchased Makena directly from AMAG. Therefore, Plaintiffs cannot maintain an unjust enrichment claim.

Count Eight is dismissed without prejudice.

V. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss is granted. The dismissal is without prejudice, and Plaintiffs are granted thirty (30) days to file an amended complaint that cures the deficiencies noted herein. If Plaintiffs fail to file an amended complaint within the allotted time, the dismissal will be with prejudice. An appropriate Order accompanies this Opinion.

All Citations

Slip Copy, 2021 WL 2103287

Footnotes

1 Defendants' motion to dismiss, D.E. 25 ("Br."); Plaintiff's opposition, D.E. 32 ("Opp."); and, Defendants' reply in further support of their motion to dismiss, D.E. 35 ("Reply").

2 Makena was developed pursuant to the Orphan Drug Act, 21 U.S.C. § 360aa. *Id*. ¶ 37. The Orphan Drug Act was intended to incentivize the development of drugs for the treatment of rare but serious conditions. *Id*. ¶ 36. According to Plaintiffs, "an 'orphan drug' is a drug used to treat a disease or condition that affects fewer than 200,000 people in the United States or lacks commercial viability." *Id*. Makena was designated an "orphan drug" in 2007.

3 Makena's FDA approved label is not attached to the Complaint. Defendant attached a copy of the label as Exhibit A to its motion to dismiss. *See* D.E. 25-2 at 5-21. Plaintiffs do not challenge the authenticity of the label or argue that the

Court should not consider the label. At the motion to dismiss stage, the Court may "consider documents attached to the complaint as well as matters of public record without converting the motion to dismiss into a summary judgment motion." *LeBoon v. Scottrade, Inc.*, 783 F. App'x 129, 131 (3d Cir. 2019) (citing *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). A court may also rely on "a document *integral to or explicitly relied* upon in the complaint." *U.S. Express Lines Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002) (emphasis in original) (citation omitted). A court in this district recently took judicial notice of an FDA-approved drug label in deciding a motion to dismiss, reasoning that "the facts in the FDA-approved drug label 'are not subject to reasonable dispute because' those facts 'can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned,' like the FDA." *In re Amarin Corp. PLC Sec. Litig.*, No. 319CV06601BRMTJB, 2021 WL 1171669, at *11 (D.N.J. Mar. 29, 2021) (collecting cases where FDA labels were considered at the motion to dismiss stage). As a result, the Court considers the Makena's FDA approved label.

4 Even assuming the merits of Defendant's argument, AMAG fails to explain why it would *not* be required to inform the FDA that its product was not effective if it received after-the-fact information to that effect. It may not be in AMAG's business interest to do so, but that is an entirely different issue.

5 In the FAC, Plaintiffs use both "Meis" and "Meiss" in reference to the author of the study. *Compare* FAC at 8, n. 8 *with id*. ¶ 64. A review of the study indicates the proper spelling is Meis. Accordingly, the Court will use the "Meis" spelling unless quoting directly from the FAC.

6 Because the Court finds that Counts One through Seven should be dismissed as preempted, the Court does not reach Defendant's remaining arguments in support of its motion.

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