UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

KENNETH DAVISON,

Plaintiff,

v. Case No. 8:21-cv-1782-WFJ-AAS

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

_____/

ORDER DENYING MOTION TO DISMISS

This matter comes before the Court on Defendant Novartis Pharmaceuticals Corporation's motion to dismiss, Dkt. 14, filed pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim. The Court has reviewed Plaintiff Kenneth Davison's complaint, Dkt. 1, the motion to dismiss, and Plaintiff's response in opposition to the motion, Dkt. 20. The Court also received cogent oral argument from both counsel. Upon consideration, the Court denies the motion.

BACKGROUND

In his complaint, Plaintiff describes his condition of wet age-related macular degeneration, or wet AMD, a debilitating disease in which a patient slowly suffers progressive sight impairment. Dkt. 1 at 4−5. To treat this condition, Plaintiff was

prescribed and injected with a biologic ocular treatment known as Beovu, which is produced and sold by Defendant. Dkt. 1 at 3. Plaintiff received three total retinal injections of Beovu, with the first taking place on January 7, 2020, the second on February 11, 2020, and a final injection on April 8, 2020. Dkt. 1 at 4.

Plaintiff alleges that, as a proximate result of this Beovu treatment, he sustained permanent ocular injuries. Dkt. 1 at 25−26. Specifically, he claims that this drug caused retinal vasculitis, retinal vascular occlusion, and related sequelae, all of which are permanent impairments of the retinal vein system. Dkt. 1 at 25−26. Plaintiff also alleges that the Beovu treatment left him permanently blind in his left eye. Dkt. 20 at 5. Plaintiff contends that there were no warnings within Beovu's product labeling regarding these risks when he was treated between January 2020 and April 2020. Dkt. 1 at 26, 28. In June 2020, however, Beovu's product labeling was updated to include warnings about the specific injuries that Plaintiff sustained. Dkt. 1 at 10−11.

As a Florida resident, Plaintiff brings his three-count complaint under Florida law.[1] Dkt. 1-1 at 1. This Court has jurisdiction due to diversity of citizenship of the parties. Doc. 1-1 at 1; 28 U.S.C. §1332. In Count I, Plaintiff brings a claim of strict liability under a failure to warn theory. Dkt. 1 at 26. He

[1]Plaintiff consented to the dismissal of a fourth count alleging unjust enrichment. That claim is no longer pertinent. Dkt. 20 at 1 n.1.

contends that Beovu was defective and unreasonably dangerous because Defendant failed to provide sufficient warnings of the risks associated with its use. Dkt. 1 at 26. Plaintiff claims that Defendant failed to provide adequate warnings or instructions to put the general public and treating physicians, including himself and his doctor, on notice of these dangers. Dkt. 1 at 26.

Next, Plaintiff alleges negligence in Count II. Dkt. 1 at 29. Tracking similar facts underlying Count I, Plaintiff contends that Defendant failed to adhere to the appropriate standard of due care and thereby negligently failed to provide accurate and clinically relevant information about Beovu. Dkt. 1 at 30. Specifically, Plaintiff argues that Defendant was negligent in failing to review pertinent medical literature, failing to disclose results of testing, representing that Beovu was safe for use, failing to conduct post-marketing studies and heed post-marketing data, and generally downplaying the risks of Beovu. Dkt. 1 at 31−32.

Lastly, Count III alleges negligent misrepresentation. Dkt. 1 at 33. Plaintiff argues that Defendant knew or should have known that the representations it made regarding Beovu's safety, efficacy, and side effects were false. Dkt. 1 at 33. Plaintiff explicitly contends that Defendant "negligently made misrepresentations and/or actively concealed, suppressed, or omitted . . . material information with the intention and specific desire to induce consumers and the medical community, including Plaintiff and Plaintiff's healthcare providers, to use, prescribe, and

purchase Beovu." Dkt. 1 at 33−34.

Defendant filed a comprehensive Rule 12(b)(6) motion to dismiss Plaintiff's complaint for failure to state a claim. Dkt. 14. Defendant primarily argues that allegations concerning any misrepresentation of Beovu's safety are preempted by the "fraud on the FDA" logic of *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352−53 (2001). Additionally, Defendant points to *Rayes v. Novartis Pharms. Corp.*, No. 5:21-cv-201, 2021 WL 2410677, at *5 (C.D. Cal. June 11, 2021), a recent case in which a federal district court dismissed similar claims regarding Beovu. The *Rayes* court determined that any dispositive new information regarding Beovu's risks arose after the *Rayes* plaintiff's injections took place. *Id.* In its motion, Defendant argues that Plaintiff stands in the same posture as the *Rayes* plaintiff, as there were not enough adverse event reports or publications before or during Plaintiff's treatment to require Defendant to change its product labeling. Dkt. 14 at 17−19. Relatedly, Defendant contends that there were insufficient reports of Beovu's adverse effects at the time Plaintiff was treated to conclude that a causal association existed between Beovu and these ocular injuries. Dkt. 14 at 18−19.

Moreover, Defendant argues that Plaintiff's Count III negligent misrepresentation claim should be dismissed because it fails the particularity requirement of Fed. R. Civ. P. 9(b). Dkt. 14 at 21. Defendant notes that, given

that Count III sounds in fraud, it must be pled with particularity under this rule. Dkt. 14 at 21. Defendant asserts that Plaintiff has not specifically identified Defendant's false statements or explained how they were false. Dkt. 14 at 22.

In his response to Defendant's motion, Plaintiff argues that his case is distinguishable from the *Rayes* case upon which Defendant relies because Plaintiff received his Beovu injections months after the *Rayes* plaintiff. Dkt. 20 at 7−8. Plaintiff contends that this timing makes all the difference, as the newly acquired information relevant in both cases arose before Plaintiff completed his course of treatment, whereas this information came to light after the *Rayes* plaintiff's treatment. Dkt. 20 at 7−8. This newly acquired information that Plaintiff cites includes a large number of anecdotal reports, four publications, including one from the American Society of Retinal Specialists, and statements made by Defendant, all of which arose after the issuance of Beovu's original product labeling but before Plaintiff's final Beovu injection. Dkt. 1 at 10−12; Dkt. 20 at 8−11.

Plaintiff argues that this newly acquired information allowed for Defendant to utilize the federal "changes being effected" ("CBE") regulation that permits a drug manufacturer to ramp up its product labeling warnings without prior approval from the FDA. Dkt. 20 at 6−7. According to Plaintiff, Defendant impermissibly failed to change Beovu's label despite being able to under the CBE regulation. Dkt. 20 at 6−7. Plaintiff also clarifies that he is not bringing a "fraud on the FDA"

claim; given that where there is sufficient newly acquired information, the *Buckman* preemption doctrine has no application.[2] Dkt. 20 at 13−14. Rather, Plaintiff claims that the newly acquired information triggered Defendant's duty to immediately remedy the deficient warning label without waiting for the FDA's permission. Dkt. 20 at 7−9.

As to Defendant's argument regarding Count III, Plaintiff maintains that he has satisfied Rule 9(b)'s specificity requirement as understood by the Eleventh Circuit. Dkt. 20 at 16 (citing *Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1371 (11th Cir. 1997)). He states that his negligent misrepresentation claim specifically discusses the omitted warnings on Beovu's initial product labeling relating to the injuries he suffered, as well as the ongoing data that Defendant received regarding these injuries. Dkt. 20 at 16−17. Plaintiff asserts that he specifically pled both what the content of the omitted warnings should have been and how Plaintiff sustained ocular injuries as a result of those omissions. Dkt. 20 at 16−17. He also states that he pled detailed facts pertaining to the ongoing data that Defendant received, demonstrating Defendant's knowledge of

[2]At this stage, the Court need not delve into the various regulatory provisions, *see* 21 C.F.R. §§ 314.70(c)(6) & 201.57(c)(6), that permit and/or require a drug manufacturer to upgrade warnings with or without FDA approval. However, the CBE regulation that is relevant here "permits drug manufacturers to change a label to reflect newly acquired information if the changes add or strengthen a . . . warning for which there is evidence of a causal association, without FDA approval." *Merck Sharpe & Dohme v. Albrecht,* 139 S. Ct. 1668, 1679 (2018) (internal quotations omitted).

the risks of Beovu and thereby showing the necessity of new warnings. Dkt. 20 at 16−17. Additionally, Plaintiff notes that he identified the times and manners in which Defendant received many adverse event reports during the months between the FDA's approval of the initial Beovu label and Plaintiff's injuries. Dkt. 20 at 16−17. Finally, Plaintiff contends that he stated with particularity the data showing that Defendant's statements to the general public and treating physicians were either false or negligent to the point of reckless indifference. Dkt. 20 at 17.

LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss for failure to state a claim, a plaintiff must plead sufficient facts to state a claim that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This standard does not require detailed factual allegations, but it demands more than an unadorned accusation. *Id.* When considering a Rule 12(b)(6) motion to dismiss, a court accepts all factual allegations of the complaint as true and construes them in the light most favorable to the plaintiff. *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). Courts should limit their "consideration to the well-pleaded factual allegations, documents central to or referenced in the complaint, and matters judicially noticed." *La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004).

ANALYSIS

The contours of Defendant's motion are well illustrated by comparing the

aforementioned *Rayes* case, which dismissed with prejudice similar claims regarding Beovu, with several recent cases from Nebraska, consolidated as *Harris v. Novartis Pharms. Corp.,* No. 4:21-cv-3013 (D. Neb. Sept. 8, 2021) (denying motion to dismiss similar claims pertaining to Beovu). *Rayes* and *Harris* differ only slightly on the facts. Neither suggests that Defendant should prevail on its motion. Although the *Rayes* court gave a strong reading to the preemptive language in *Buckman,* the main reason that the *Rayes* plaintiff lost was due to the lack of newly acquired information arising between the FDA's approval of Beovu's initial product labeling and the plaintiff's subsequent treatment. 2021 WL 2410677, at *5−6. The timeline differed in *Harris*; in denying a similar motion to dismiss, the *Harris* court noted that some new adverse event reports and other data preceded the plaintiffs' Beovu injections. No. 4:21-cv-3013, at *10. The Harris court also found that the plaintiffs' claims were not "fraud on the FDA" claims and, therefore, were not preempted. *Id.* at *6.

Here, Plaintiff is correct that a substantial amount of adverse information regarding Beovu was disseminated after the *Rayes* plaintiff received his last Beovu treatment (January 20, 2020), but during Plaintiff's course of treatment (between January 7, 2020 and April 8, 2020). *See* Dkt. 1 at 21−25; Dkt. 20 at 2−4. This new adverse information includes a "safety signal" for these retinal vein system risks, which was published by Defendant on April 8, 2020, but obviously considered

internally by Defendant prior to that date.[3] Dkt. 1 at 10. Two months later, Defendant issued a revised Beovu warning label concerning these precise risks of injury. Dkt. 1 at 10.

Given the standard for dismissal, the Court finds that Plaintiff's complaint may stand as written. Plaintiff meets all required elements for pleading his three claims under Florida law. The facts that Plaintiff alleges are substantial and lucid. Perhaps acknowledging this, Defendant does not argue missing elements or implausible facts but, rather, urges preemption of these claims and a lack of specificity as to Count III. The complaint is clear; it is not missing elements, and it states plausible claims. Plaintiff's complaint ultimately puts Defendant on clear notice of what it must defend.

Moreover, despite Defendant's arguments of preemption, dismissal is not warranted for three reasons. First, like the complaint in *Harris*, a full and fair reading of the present complaint shows that it does not plainly allege a "fraud on the FDA" case. *See* No. 4:21-cv-3013, at *9. Perhaps an ocular metaphor is inapt here, but one must squint with a jaundiced eye to conclude that the gravamen of the instant complaint amounts to "fraud on the FDA." Rather, the complaint essentially reads like a standard Florida pharmaceutical failure to warn case. In

[3] A "safety signal" is an FDA-mandated public surveillance notification that indicates that there is evidence to support a causal relationship between a drug and ingestion-related injury. *See* Dkt. 20 at 8 n.35 (citing FDA authority).

this regard, Defendant urges the Court to infer that which Plaintiff does not expressly state. At this stage, the Court should not divine a standalone "fraud on the agency" case when the complaint does not clearly read that way. That Plaintiff should be put out of court and barred from pursuing his claims on that basis is a conclusion that can only be reached through strong inferences. Furthermore, the undersigned does not understand Defendant to be arguing that the FDA's actions regarding Beovu rendered Defendant's compliance with Florida tort law impossible, such that "impossibility preemption" applies here.

Second, it is not certain that *Buckman* applies to this case as a legal rule. In *Buckman*, the Supreme Court held that state law claims premised on "fraud on the FDA" are preempted because they conflict with "the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350. While *Buckman* appears analogous, it is not controlling at this stage. Unlike Plaintiff's case, *Buckman* was a pure "fraud on the agency" claim. Moreover, *Buckman* involved medical devices. *Id.* at 343. Medical devices are subject to a special statute called the Medical Device Amendment, 21 U.S.C. § 360c et. seq., which includes an express preemption and an implied preemption for state law claims regarding such devices. *Buckman*, 531 at 352.[4] Here, Congress has not

[4]As the Eleventh Circuit has explained, the Medical Device Amendment both expressly and impliedly preempts certain state law. *Godelia v. Doe 1*, 881 F.3d 1309, 1317 (11th Cir. 2018) citing 21 U.S.C. 360K(a); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1333 (11th Cir. 2017).

enacted an express preemption for prescription drugs. *Wyeth v. Levine,* 555 U.S. 555, 567 (2009).

Third, at this stage, the facts are not illuminated. Although some issues of preemption may be a purely legal questions for the Court,[5] the underlying facts that drive those issues are not developed and remain in dispute. As such, dismissal is not warranted at this point in the proceedings.

Turning to Defendant's Rule 9(b) argument regarding Count III, the Court agrees that Plaintiff's negligent misrepresentation claim was not richly pled in terms of facts. However, it satisfies Rule 9(b). "The purpose of Rule 9(b)'s particularity requirement is to 'alert[] defendants to the precise misconduct with which they are charged and protect[] defendants against spurious charges of immoral and fraudulent behavior.'" *Hills v. Morehouse Med. Assocs., Inc.*, 2003 WL 22019936, at *3 (11th Cir. Aug. 15, 2003) (citing *Ziemba v. Cascade Int'l, Inc.,* 256 F.3d 1194, 1202 (11th Cir. 2001)). Count III accomplishes this task.

The Rule 9(b) specificity requirement is also intended to avoid giving a plaintiff a ticket to "fish" in discovery when he cannot set forth fraudulent activity in the initial pleadings. *In re Checkers Sec. Litig.*, 858 F. Supp. 1168 (M.D. Fla. July 5, 1994). That concern is lessened here, given the other viable claims that are

[5] *See, e.g., Albrecht*, 139 S. Ct. at 1680 (determining that impossibility preemption is purely a legal question for the judge).

going forward. Additionally, it is clear on this record that Defendant will be defending exactly this cause of action and providing near-identical discovery in other jurisdictions. Ultimately, the Court does not find Count III so devoid of content that it needs to be stricken or repled. As with the other claims, if Defendant's theories on Count III are as strong as Defendant now urges, those defenses will strengthen with factual testing and may fare well at the summary judgment stage.

CONCLUSION

Accordingly, Defendant's motion to dismiss, Dkt. 14, is denied. The agreed removal of Count IV should not require repleading: it will just be treated as surplusage. Defendant should file its answer to Plaintiff's complaint, Dkt. 1, within 14 days.

DONE AND ORDERED at Tampa, Florida, on September 23, 2021.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE

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Counsel of Record