IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF VIRGINIA

Richmond Division

MARTHA BARRY,
Plaintiff,

v. Civil No. 3:22cv196 (DJN)

NOVARTIS PHARMACEUTICALS CORP.,
Defendant.

MEMORANDUM OPINION
(Granting in Part and Denying Motion to Dismiss and Granting Judicial Notice Requests)

Plaintiff Martha Barry ("Plaintiff") brings this action against Defendant Novartis Pharmaceuticals Inc. ("Defendant"), alleging strict liability for failure to warn, negligence, fraudulent misrepresentation, negligent misrepresentation and punitive damages, all under Virginia law. This matter now comes before the Court on Defendant's Motion to Dismiss Plaintiff's Complaint (ECF No. 10), Defendant's Request for Judicial Notice in Support of Its Motion to Dismiss ("Def.'s Judicial Notice Request" (ECF No. 12)) and Plaintiff's Request for Judicial Notice in Support of Her Opposition to the Motion to Dismiss ("Pl.'s Judicial Notice Request" (ECF No. 22)).

For the reasons set forth below, the Court will grant in part and deny in part the Motion to Dismiss. Specifically, the Court will grant the Motion as to Count One, but not for the reasons that Defendant argues in its Motion. Further, the Court will grant the Motion as to the portions of Plaintiff's fraud-based claims (Counts Three and Four) regarding Defendant's advertising encouraging healthcare providers to switch their patients to Beovu. As it relates to all other

claims, the Motion to Dismiss will be denied. Additionally, the Court will grant Plaintiff's and Defendant's requests for judicial notice.

I. BACKGROUND

At this stage, the Court must accept as true the facts set forth in the Complaint (ECF No. 1). *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Against this backdrop, the Court accepts the following facts as alleged for purposes of resolving the instant Motion.

A. Factual Background

The drug brolucizumab, sold under the registered trademark Beovu, functions as a human vascular endothelial growth factor ("VEGF") inhibitor indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration ("AMD") in adults. (Compl. ¶ 21.) AMD, a chronic eye disease, causes leakage and accumulation of fluid within the retina that results in visual impairment. (Compl. ¶ 22.) Beovu is administered as an intravitreal injection, and it treats AMD by inhibiting the binding of VEGF to certain receptors, thereby suppressing the growth of abnormal blood vessels and reducing the potential for fluid leakage into the retina. (Compl. ¶ 34.)

Defendant, a subsidiary of Novartis AG, has its place of incorporation in Delaware and its principal place of business in New Jersey. (Compl. ¶ 6.) Defendant currently sponsors the Biologics License Application for Beovu, and as such, has primary responsibility and control over the drug and all activities and materials related to it. (Compl. ¶ 6.) Specifically, Plaintiff alleges that, "[a]t all times relevant, Defendant[] [was] engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or

advertising for sale . . . Beovu for use by physicians in treating their patients, including Plaintiff." (Compl. ¶ 18.)

The United States Food and Drug Administration ("FDA") accepted Defendant's BLA for Beovu on April 15, 2019. (Compl. ¶ 31.) The FDA approved Beovu in October 2019. (Compl. ¶ 32.) The FDA had previously approved two other VEGF inhibitors for the treatment of AMD in 2006 and 2011. (Compl. ¶ 35.)

Patients treated with Beovu have experienced several acute eye injuries — namely, retinal vasculitis, retinal vascular occlusion and uveitis — that those treated with other anti-VEGF drugs have not. (Compl. ¶¶ 40, 42.) These conditions occur extremely rarely in the absence of drug use. (Compl. ¶ 70.) Retinal vasculitis, an inflammation of the vessels of the retina that often leads to a decrease in vision, can lead to retinal vascular occlusion and/or retinal artery occlusion.[1] (Compl. ¶ 41.) Retinal vascular occlusion constitutes an obstruction of the venous or arterial system of the retina, usually by a thrombus or embolus, resulting in vision loss that can become severe or permanent. (Compl. ¶ 41.) Uveitis, or inflammation in the uvea, provides the general medical term for intraocular inflammation that subsumes and/or occurs in conjunction with retinal vasculitis. (Compl. ¶ 43.)

Plaintiff, a resident of Colonial Heights, Virginia, was prescribed and injected with Beovu on February 12, 2020, and April 21, 2020. (Compl. ¶¶ 5, 15.) After her second Beovu injection, she began to develop severe vision problems, and on May 6, 2020, she received a diagnosis of retinal vasculitis and uveitis. (Compl. ¶ 15.) She received treatment for her Beovu-related injuries in this District. (Compl. ¶ 5.)

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[1] The Court refers to both retinal vascular and retinal artery occlusion as "retinal vascular occlusion" herein.

Beovu's product labeling contained no warnings of retinal vasculitis or retinal vascular occlusion before Plaintiff received either of her injections. (Compl. ¶ 76; *see also* Def.'s Judicial Notice Req. Ex. A ("October 2019 Beovu Labeling") at 2, 6 (listing warnings and precautions, which did not include retinal vasculitis, retinal vascular occlusion or uveitis).) On June 9, 2020, just a few months after Plaintiff's final injection, Defendant updated Beovu's product label to include a new warning of the risks of retinal vasculitis and/or retinal vascular occlusion. (Compl. ¶ 74.)

However, Defendant had begun to receive post-marketing adverse event reports related to retinal vasculitis, uveitis and retinal vascular occlusion almost immediately after Beovu came on the market and long before it included these risks on the product's label. (Compl. ¶ 53.) The first report came on November 13, 2019, and detailed an incidence of retinal vascular occlusion in a Beovu patient who experienced serious and disabling injuries. (Compl. ¶ 54.) Defendant continued to receive similar adverse event reports from December 2019 through April 2020, before Plaintiff's last injection of Beovu on April 21, 2020, totaling 202 reports. (Compl. ¶¶ 56-65.) In many of these reports, the reporting physician causally attributed the patients' injuries to Beovu. (Compl. ¶ 66.) Similarly, before Plaintiff's last Beovu exposure, peer-reviewed medical literature noted the causal connection between Beovu and vision-related injuries.[2] (Compl. ¶ 49

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[2] In this vein, Plaintiff alleges that, on April 7, 2020, the American Society of Retina Specialists Research and Safety in Therapeutics Committee published an article, *Occlusive Retinal Vasculitis Following Intravitreal Brolucizumab*, that noted a causal relationship between Beovu and retinal vasculitis and advised providers to use caution when administering the drug. (Compl. ¶¶ 51-52.) However, this report was not published until July 1, 2020. Andre J. Witkin *et al.*, *Occlusive Retinal Vasculitis Following Intravitreal Brolucizumab*, 4 J. Vitreoretinal Diseases 269 (2020) (author manuscript), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7418897/pdf/nihms-1615442.pdf. The Court normally cannot consider extrinsic documents on a Rule 12(b)(6) motion to dismiss, but because Plaintiff incorporates this article into the Complaint by reference, the Court may rely on it. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007) (holding that the court may

(citing Sara J. Haug *et al.*, *Retinal Arterial Occlusive Vasculitis Following Intravitreal Brolucizumab Administration*, 18 Am. J. of Ophthalmology Case Reports (Mar. 31, 2020).) [3]

Additionally, Defendant also acknowledged the vision-related risks of Beovu before Plaintiff's last exposure to the drug. On January 17, 2020, a Defendant-funded review of brolucizumab was published. (Compl. ¶¶ 98-100.) In this review, several of Defendant's current or former employees reanalyzed pre-approval clinical trial data and noted that the drug could cause retinal vasculitis and significant vision loss. (Compl. ¶¶ 98-99 (quoting Quan Don Nguyen *et al.*, *Brolucizumab: Evolution Through Preclinical and Clinical Studies and the Implications for the Management of Neovascular Age-Related Macular Degeneration*, 127 Translational Sci. Rev. 963, 974 (Jan. 17, 2020).)[4] Further, on April 8, 2020, Defendant confirmed the existence of a safety signal involving rare adverse events of retinal vasculitis and retinal vascular occlusion resulting in severe vision loss for Beovu and stated that it would update the Beovu label worldwide based on this safety signal. (Compl. ¶ 71.)

Finally, on June 9, 2020, Defendant changed the Beovu label to include a warning regarding the risk of retinal vasculitis and retinal vascular occlusion. (Compl. ¶ 74.) Plaintiff asserts that Beovu's label should have been updated sooner, because this information constitutes

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consider documents incorporated by reference when deciding a Rule 12(b)(6) motion). Where the bare allegations of the complaint conflict with any document incorporated therein, the document prevails. *Fayetteville Invs. v. Com. Builders, Inc.*, 936 F.2d 1462, 1465 (4th Cir. 1991). Since such a conflict exists here, the Court will deem July 1, 2020, as this article's publication date.

[3] Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7125319/pdf/main.pdf.

[4] Available at https://www.aaojournal.org/article/S0161-6420(20)30041-5/fulltext.

newly acquired information that should have prompted Defendant to include a warning about retinal vasculitis, uveitis and retinal vascular occlusion. (Compl. ¶ 72.)[5]

B. Plaintiff's Complaint

On April 11, 2022, Plaintiff filed her Complaint against Defendant, raising five counts for relief based on the above allegations.[6] Count One asserts a claim of strict liability for failure to warn, alleging that Beovu was defective and unreasonably dangerous, because it failed to contain warnings of an adequate or sufficient nature to alert consumers and physicians to the dangerous risks associated with the product, and Defendant concealed these risks. (Compl. ¶¶ 103-16.) Count Two asserts negligence, alleging that Defendant breached its duties to Plaintiff by failing to provide Plaintiff, other consumers, physicians and the public with accurate information about the risks of Beovu, failing to provide post-marketing warnings after adverse incidents came to light and downplaying the risks of Beovu, among other ways. (Compl. ¶¶ 117-24.)

Counts Three and Four assert fraudulent and negligent misrepresentation, respectively, alleging that Defendant intentionally or negligently made material misrepresentations and omissions regarding the safety and efficacy of Beovu and its side effects to Plaintiff and her healthcare providers. (Compl. ¶¶ 125-74.) Virginia law does not recognize negligent fraud as a cause of action separate and apart from constructive fraud. *Baker v. Elam*, 883 F. Supp. 2d 576,

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[5] Furthermore, the Beovu label included information regarding these conditions only in its "Clinical Trials Experience" section, which inaccurately reflected that 1% of clinical trial patients experienced these injuries. (Compl. ¶ 113.) Rather, at least 3.3% of clinical trial patients had experienced these injuries. (Compl. ¶ 113.) In fact, the Beovu label failed to reflect that the drug's clinical trials demonstrated a 2,312% increased risk of retinal vasculitis or retinal vascular occlusion relative to those patients that used aflibercept, the active control, in clinical trials. (Compl. ¶ 114.) Plaintiff does not specify the source of this information or its date of publication.

[6] Plaintiff also sued Novartis Institutes for BioMedical Research, Inc. ("NIBR"), but the parties stipulated to NIBR's dismissal without prejudice. (ECF No. 8.)

581 (E.D. Va. 2012); *see also Richmond Metro. Auth. v. McDevitt Street Bovis, Inc.*, 507 S.E.2d 344, 347 (Va. 1998) ("The essence of constructive fraud is negligent misrepresentation."). The Court, therefore, construes Plaintiff's negligent misrepresentation claim as a constructive fraud claim.

Count Five asserts a claim for punitive damages, alleging that Defendant intentionally misrepresented the trial data for Beovu to the FDA, healthcare providers and the general public to mask Beovu's risks, that such actions were willful and malicious, and that Plaintiff has suffered permanent losses that merit punitive damages. (Compl. ¶¶ 175-83.)

C. Defendant's Motion to Dismiss

In response to the Complaint, Defendant filed a Motion to Dismiss (ECF No. 10), moving to dismiss the Complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). In support of their Motion, Defendant asserts that federal law preempts Plaintiff's claims, that Plaintiff did not plead her fraud-based claims with particularity and that she does not adequately allege willful and wanton conduct in her claim for punitive damages. (Def.'s Mem. in Supp. of Its Mot. to Dismiss the Compl. Pursuant to Fed. R. Civ. P. 12(b)(6) ("Def.'s Mem.") at 8-17 (ECF No. 11).) On May 25, 2022, Plaintiff responded (Pl.'s Mem. in Opp'n to Def. Mot. to Dismiss ("Resp.") (ECF No. 21)), and on May 31, 2022, Defendant replied (ECF No. 24)). On June 30, 2022, the Court heard argument on the instant Motion, rendering it ripe for review.

II. STANDARD OF REVIEW

A motion to dismiss pursuant to Rule 12(b)(6) tests the sufficiency of a complaint or counterclaim; it does not serve as the means by which a court will resolve contests surrounding the facts, determine the merits of a claim or address potential defenses. *Republican Party of N.C.*

v. Martin, 980 F.2d 943, 952 (4th Cir. 1992). In considering a motion to dismiss, the Court will accept a plaintiff's well-pleaded allegations as true and view the facts in a light most favorable to the plaintiff. *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678.

Under the Federal Rules of Civil Procedure, a complaint or counterclaim must state facts sufficient to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). As the Supreme Court opined in *Twombly*, a complaint or counterclaim must state "more than labels and conclusions" or a "formulaic recitation of the elements of a cause of action," though the law does not require "detailed factual allegations." *Id.* (citations omitted). Ultimately, the "[f]actual allegations must be enough to raise a right to relief above the speculative level," rendering the right "plausible on its face" rather than merely "conceivable." *Id.* at 555, 570. Thus, a complaint or counterclaim must assert facts that are more than "merely consistent with" the other party's liability. *Id.* at 557. And the facts alleged must be sufficient to "state all the elements of [any] claim[s]." *Bass v. E.I. Dupont de Nemours & Co.*, 324 F.3d 761, 765 (4th Cir. 2003) (citing *Dickson v. Microsoft Corp.*, 309 F.3d 193, 213 (4th Cir. 2002) and *Iodice v. United States*, 289 F.3d 270, 281 (4th Cir. 2002)).

III. ANALYSIS

A. The Court Takes Judicial Notice of the Documents that Plaintiff and Defendant Provide.

First, as an initial matter, Defendant requests that the Court take judicial notice of the October 2019 drug label for Beovu (Beovu Label (ECF No. 12-1)) and the FDA's webpage regarding its Adverse Event Reporting System ("FAERS") from June 2018 (Judicial Notice Req.

Ex. B ("FAERS Webpage") (ECF No. 12-2)) under Federal Rule of Evidence 201. (Def.'s Judicial Notice Req. at 1.) Additionally, Plaintiff requests that the Court take judicial notice of the 1995 FDA document *Guideline for Industry: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting* (Pl.'s Judicial Notice Req. Ex. A ("Guideline for Industry") (ECF No. 22-1)) under the same Rule. (Pl.'s Judicial Notice Req. at 1.)

The Court will grant both of these requests. Ordinarily, for the purposes of deciding a motion to dismiss, the Court will only consider those factual allegations set forth in the Complaint. *Phillips v. LCI Int'l, Inc.*, 190 F.3d 609, 618 (4th Cir. 1999). Additionally, the Court may consider documents attached to the complaint, Fed. R. Civ. P. 10(c), as well as "documents incorporated into the complaint by reference, and matters of which the court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007). Federal Rule of Evidence 201(b)(2) allows the court to judicially notice a fact "that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Here, neither party opposes the other's request for judicial notice. Additionally, because these documents constitute FDA publications that the public can access via the FDA website, they satisfy Rule 201, and the Court will judicially notice them as it considers the Motion to Dismiss. *See Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) ("[T]he Court may take judicial notice of and consider the public records of the FDA . . . without transforming [a motion to dismiss] into a motion for summary judgment." (citations omitted)).

B. The Court Will Grant in Part and Deny in Part the Motion to Dismiss.

When adjudicating state law claims, federal courts must apply state law. *United States v. Little*, 52 F.3d 495, 498 (4th Cir. 1995) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78

(1938)). In so doing, federal courts must use state law according to how the state's highest court has interpreted the law or anticipate how that court would rule. *Horace Mann Ins. Co. v. Gen. Star Nat'l Ins. Co.*, 514 F.3d 327, 329 (4th Cir. 2008). Because Plaintiff's claims arise under Virginia law, and the Court has diversity jurisdiction over this matter, the Court must predict how the state supreme court would rule. *See id.* ("Because we are sitting in diversity, our role is to apply the governing state law, or, if necessary, predict how the state's highest court would rule on an unsettled issue." (citation omitted)).

1. Count One, strict liability for failure to warn, cannot proceed, because such a claim does not exist under Virginia law.

Count One of the Complaint alleges strict liability for failure to warn. In Virginia, "[s]trict liability attaches only to abnormally dangerous activities." *Arlington Forest Assocs. v. Exxon Corp.*, 774 F. Supp. 387, 389 (E.D. Va. 1991). It does not apply to product liability failure-to-warn claims. *Torkie-Tork v. Wyeth*, 757 F. Supp. 2d 567, 572 n.11 (E.D. Va. 2010) (citing *Harris v. T.I., Inc.*, 413 S.E.2d 605, 609-10 (Va. 1992)). Thus, the Court must dismiss Count One.

Defendant never raises this argument in briefing, and the Court does so on its own accord.[7] *See Neitzke v. Williams*, 490 U.S. 319, 327 (1989) ("[I]f as a matter of law 'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations, a claim must be dismissed . . . ." (citing *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)). Because the cause of action that Plaintiff brings in Count One does not exist, it is clear as a matter of law that the Court could not grant her relief under any set of facts, and it must dismiss this count. To be clear, however, the Court rejects Defendant's primary argument for

[7] On June 27, 2022, the Court provided notice to the parties of this issue so that counsel could prepare to address it during oral argument. (ECF No. 26.)

dismissal — that federal law preempts Plaintiff's failure-to-warn claims in their entirety. (Def.'s Mem. at 6-14.) Thus, Count Two, negligent failure to warn, may proceed, as discussed below.

2. Federal law does not preempt plaintiff's state-law failure-to-warn claims.

Defendant first argues that Plaintiff relies on pre-approval facts to claim that Defendant should have changed its label. (Def.'s Mem. at 13.) This sort of claim, according to Defendant, is preempted under *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001). (Def.'s Mem. at 13-14.) Defendant argues in the alternative that, because Plaintiff failed to allege newly acquired information, that should have triggered a label update under the "changes being effected" ("CBE") regulation, Plaintiff's failure-to-warn claims must fail. (Def.'s Mem. at 8.)

Plaintiff responds that Defendant bore the responsibility for accurate labeling of Beovu at all times but failed to fulfill this responsibility. (Resp. at 5-7.) She further contends that the adverse event reports and other information that Defendant received before her last exposure sufficed to trigger a unilateral label change, and that federal law does not preempt her claims. (Resp. at 5-17.) She also clarifies that she bases Count Three, her negligence claim, on both a failure-to-test theory, as well as a failure-to-warn theory. (Resp. at 21.)[8]

Under federal drug regulations, the manufacturer bears the responsibility for the content of its label at all times. *Wyeth v. Levine*, 555 U.S. 555, 567-68 (2009). The manufacturer must "craft[] an adequate label and . . . ensure[] that its warnings remain adequate as long as the drug

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[8] In her Response, Plaintiff attempts to characterize her failure-to-warn claims as failure-to-test claims. (Resp. at 21.) Virginia law does not recognize standalone failure-to-test claims. *Sykes v. Bayer Pharms. Corp.*, 548 F. Supp. 2d 208, 215 (E.D. Va. 2008) (finding that, because "Virginia recognizes only three ways in which a product may be unreasonably dangerous" — defective manufacture or assembly, unreasonably dangerous design or failure to warn — standalone failure-to-test claims do not exist under Virginia law). As such, the Court construes Counts One and Two as failure-to-warn claims.

is on the market." *Id.* at 571 (first citing 21 C.F.R. § 201.80(e); and then citing 73 Fed. Reg. 49605). Generally, federal regulations bar manufacturers from changing their drug labels after the label has received FDA approval. *Id.* at 568. However, FDA regulations do provide some exemptions to this rule. First, a manufacturer can secure FDA approval for a proposed change before distributing the product with the changed label. 21 C.F.R. § 314.70(b)(2)(v)(A). Second, under the CBE regulation, a manufacturer can make changes without first receiving FDA approval by sending the FDA a "supplement submission." 21 C.F.R. § 314.70(c)(6)(iii). The CBE regulation allows a manufacturer to change a drug's label without prior FDA approval for various reasons, including the receipt of "newly acquired information" that requires "add[ing] or strengthen[ing] a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under [21 C.F.R.] § 201.57(c)," or "add[ing] or strengthen[ing] an instruction about dosage and administration that is intended to increase the safe use of the drug product." 21 C.F.R. § 314.70(c)(6)(iii)(A), (C). Newly acquired information constitutes:

> data, 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.

Relevant here, 21 C.F.R. § 201.57(c)(6)(i) requires the "warnings and precautions" section of a drug's label to "describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug)." Further, under this regulation, "the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of

a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i).

The United States Constitution's Supremacy Clause provides that federal law "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. In the absence of an express preemption provision, federal law impliedly preempts state law "where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 480 (2013) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). In this context, the "underlying question [becomes] whether federal law (including appropriate FDA actions) prohibited the drug manufacturer from adding any and all warnings to the drug label that would satisfy state law." *Knight v. Boehringer Ingelheim Pharm., Inc.*, 984 F.3d 329, 337 (4th Cir. 2021) (quoting *Merck Sharp & Dohme Corp. v. Albrecht,* 139 S. Ct. 1668, 1672 (2019)). State-law challenges to FDA-approved warnings, such as tort actions under state law, "can thus proceed only when the defendant had the unilateral ability to change that labeling; otherwise, the claim is preempted." *Id.*

a. Federal law does not preempt Plaintiff's claims under *Buckman*.

The Court disagrees with Defendant that *Buckman* preempts Plaintiff's failure-to-warn claim. In *Buckman*, the plaintiff brought state-law claims alleging that the defendant, a consulting company for a drug manufacturer, made fraudulent representations to the FDA when seeking regulatory approval for the manufacturer's orthopedic bone screws. *Buckman*, 531 U.S. at 343. The Supreme Court held that federal law preempted plaintiff's state-law fraud claims, explaining that federal law authorizes only the federal government to sue for noncompliance with medical device regulations, and that "[s]tate-law fraud-on-the-FDA claims inevitably

conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objections." *Id.* at 349 n.4, 351.

Buckman does not spell dismissal for Plaintiff. Unlike *Buckman*, which clearly involved fraud-on-the-FDA claims, this case involves allegations that Defendant failed to update Beovu's labeling, thereby making false representations regarding Beovu's risks to physicians and consumers after receiving FDA approval. (Compl. ¶¶ 118, 120, 123.) "State-law negligence and strict liability claims premised on a duty to warn consumers or their physicians are not preempted, even when that duty 'parallels' federal requirements." *Rayes v. Novartis Pharms. Corp.*, 2022 WL 822195, at *1 (9th Cir. Mar. 18, 2022) (citations omitted) (reversing dismissal of state-law failure-to-warn claims involving Beovu, because federal law did not preempt those claims); *Watler v. Novartis Pharms. Corp.*, 2022 WL 971948, at *3 (M.D. Fla. Mar. 31, 2022) (in virtually identical Beovu case, rejecting defendant's argument that federal law preempted plaintiff's claims); *Davison v. Novartis Pharms. Corp.*, 2021 WL 4340412, at *4 (M.D. Fla. Sept. 23, 2021) (same); *Harris v. Novartis Pharms. Corp.*, Mem. & Order ("*Harris* Mem. & Order") at 8-9, No. 8:21cv32 (D. Neb. Sept. 8, 2021) (ECF No. 51) (same). As such, Count Two survives the instant Motion.

Indeed, Plaintiff does allege that Defendant underreported the observed incidences of vision-related injuries in Phase III clinical trial data that Defendant originally reported to the FDA in its approval application. (Compl. ¶ 135.) However, these allegations merely illustrate "[D]efendant's state of mind — what [D]efendant knew and when [D]efendant knew it —" rather than bolstering a fraud-on-the-FDA claim. *Harris* Mem. & Order at 9 (D. Neb. Sept. 8,

2021) (No. 8-21cv32) (ECF No. 51).[9] Plaintiff's Complaint centers on the misrepresentations that Defendant made to her and her physician, as well as other patients, healthcare providers and the public due to its failure to update its label pursuant to the CBE regulation — not misrepresentations made to the FDA. *See Davison*, 2021 WL 4340412, at *4 ("[O]ne 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 failure to warn case.") For these reasons, federal law does not preempt Plaintiff's claims.

3. At this stage, Plaintiff demonstrates that newly acquired information supported a unilateral label change by Defendant.

Second, the Court finds that Plaintiff sufficiently alleges that Defendant should have unilaterally updated its label based on newly acquired information about the risks of Beovu. For this additional reason, the Court finds that federal law does not preempt Plaintiff's claims.

Here, Plaintiff highlights several sources of information that arose after the FDA approved Beovu and before her last exposure, demonstrating a causal connection between ocular injuries and Beovu. She alleges that Defendant received 23 or more adverse event reports before Plaintiff's first Beovu injection. (Compl. ¶¶ 54-58.) In February 2020, it received 53 adverse event reports involving the drug, but the Complaint does not specify whether these events

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[9] In fact, the FDA regulations themselves contemplate the possibility that approval applicants may present inaccurate findings to the FDA when seeking approval and later seek to update their drug's label based on new information. As discussed previously, newly acquired information that should trigger a label change under the CBE regulation includes "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. In other words, this regulation recognizes the possibility that results of data analyses previously submitted to the FDA may not have accurately captured the risks of a particular drug. Thus, Plaintiff's allegation that a Defendant-funded study reanalyzed old data to reveal new risks about Beovu does not automatically transform her Complaint into a fraud-on-the-FDA claim.

occurred before or after Plaintiff's first injection on February 12, 2020. (Compl. ¶¶ 60-61.) Regardless, Defendant continued to receive adverse event reports after Plaintiff's first injection, receiving a total of 202 adverse event reports before her final exposure to Beovu. (Compl. ¶¶ 54-65.) Many of these reports contained causal contributions to patients' use of Beovu. (Compl. ¶ 66.)

Further, Plaintiff alleges that, before her last exposure, current or former employees of Defendant co-authored and published a study re-analyzing Defendant's clinical trial data on Beovu. (Compl. ¶¶ 98-100 (citing Nguyen *et al.*, *supra*).) This study demonstrated a causal relationship between the drug and ocular inflammation, including occlusive retinal vasculitis and vision loss. (Compl. ¶¶ 98-100 (citing Nguyen *et al.*, *supra*).) Other medical literature and groups also began to recognize the vision-related risks of Beovu before Plaintiff's last exposure, as well. (Compl. ¶¶ 44-50.) Likewise, on April 8, 2020, Defendant confirmed the existence of a safety signal regarding retinal vasculitis, retinal vascular occlusion and severe vision loss and stated that it would seek to update Beovu's labeling. (Compl. ¶ 71.) Despite this information, Defendant did not change Beovu's label to include a warning about these risks until June 2020, nearly two months after Plaintiff's last injection. (Compl. ¶¶ 74-76; Oct. 2019 Beovu Label at 6.) At this stage, the Court finds that this information constitutes newly acquired information that should have triggered a label change under the CBE regulation, and that federal law does not preempt Plaintiff's claims.

Defendant takes issue with this information, arguing that, to constitute newly acquired information, Plaintiff must allege information that "offer[s] 'some basis to believe there is a causal relationship'" between Beovu and the alleged injuries. (Reply at 3.) This argument fails,

because the information that Plaintiff highlights contained discussion of the causal relationship between visual injuries and Beovu. (Compl. ¶¶ 98-100.)

Further, Defendant contends that such newly acquired information must also "reveal risks of a different type or a greater severity or frequency," pursuant to federal regulations. (Reply at 2-3 (quoting 21 C.F.R. § 601.12(f)(6)); *see also* Def.'s Mem. at 11 (citing *MacMurray v. Boehringer Ingelheim Pharms., Inc.*, 2017 WL 11496825, at *7-8 (D. Utah Dec. 6, 2017) (finding 73 adverse event reports insufficient to establish "newly acquired information," because the complaint did not allege that this information did not indicate a change in severity or frequency of adverse events).) Because the Complaint neither alleges such an increase, or facts from which the Court could infer one, Defendant argues that the information that Plaintiff notes does not constitute newly acquired information. (Def.'s Mem. at 11-13.)

Both in briefing and during oral argument, Defendant pointed to the Fourth Circuit's recent *Knight* decision to argue that, because Plaintiff did not expressly plead that new information revealed risks of a different type or greater severity or frequency than previously included in submissions to the FDA, she cannot argue that the CBE regulation enabled Defendant to unilaterally change its label. (Reply at 3 (citing *Knight*, 984 F.3d 329).) In *Knight*, the plaintiffs brought state-law product liability claims against the manufacturer of a Pradaxa, a blood thinner, after their mother died from a gastrointestinal bleed caused by the drug. *Knight*, 984 F.3d at 332-33. Before the decedent used Pradaxa, the defendant manufacturer warned on the drug's label that it could cause serious and sometimes fatal bleeding, and that bleeding was one of its most common adverse reactions. *Id.* at 334. According to the plaintiffs, this label did not provide an adequate warning. *Id.* at 332. They asserted that, before their mother's exposure, scientists for the defendant working on a post-approval study had made some preliminary

findings that certain Pradaxa patients might require regular monitoring of the concentration of Pradaxa in their blood to prevent bleeding. *Id.* at 338-39. These preliminary findings, they argued, should have caused the defendant to strengthen the warning about bleeding on Pradaxa's label. *Id.* at 338.

The jury returned a verdict for the defendant on all claims except the state-law fraud claim. *Id.* at 336. Subsequently, the defendant moved for judgment as a matter of law, arguing that federal law preempted the fraud claim, because the plaintiffs had not identified newly acquired information that would trigger a label change under the CBE regulation. *Knight*, 984 F.3d at 338. The district court denied the motion, and the Fourth Circuit reversed. *Id.* at 337, 341. According to the Fourth Circuit, the study that Plaintiff had identified did not reveal risks of a different type or greater severity or frequency than that previously submitted to the FDA. *Id.* at 338, 341. It explained that the FDA already knew of the correlation between Pradaxa blood concentration levels and bleeding risk. *Id.* at 338. In particular, when approving Pradaxa, the FDA acknowledged the significant relationship between Praxada exposure and bleeding, as well as the fact that Pradaxa increased the probability of life-threatening bleeds. *Id.* at 338. Further, Pradaxa's physician label had warned of renal impairment. *Id.* at 339. Thus, since the FDA knew of the risk of bleeding that the study identified but "nonetheless did not require the defendants specifically to warn of it in the label," the Fourth Circuit concluded that the CBE regulation did not apply. *Id.* at 338. For that reason, federal law preempted the fraud claim. *Id.* at 341.

Knight is distinguishable from this case. Here, Plaintiff alleges Beovu's product labeling contained no warnings of retinal vasculitis or retinal vascular occlusion before Plaintiff received either of her injections. (Compl. ¶ 76; *see also* October 2019 Beovu Labeling at 2, 6 (listing

warnings and precautions, which did not include retinal vasculitis, retinal vascular occlusion or uveitis).) However, Defendant had received 202 adverse event reports, many of which contained causal attributions, before Plaintiff's last exposure to Beovu. (Compl. ¶¶ 54-66.) Further, Defendant's own reanalysis of clinical trial data that it presented to the FDA — which was published before Plaintiff's last exposure to Beovu — revealed a causal relationship between Beovu and Plaintiff's alleged injuries. (Compl. ¶¶ 98-100 (citing Nguyen *et al.*, *supra*).) Likewise, on April 8, 2020, Defendant published a safety signal for Beovu, which stated that it could cause retinal vasculitis, retinal vascular occlusion and severe vision loss, and advised that it would seek to update Beovu's labeling based on the safety signal. (Compl. ¶ 71.)

This information warranted an update to Beovu's label, which did not warn patients and healthcare providers about these risks at the time of Plaintiff's injections. Federal regulations require a drug's label to "be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). Before Plaintiff's exposure to Beovu, the label did not include any warnings about the causal association between the drug and the alleged risks. (Compl. ¶ 76; October 2019 Beovu Labeling at 2, 6.) After the FDA approved the drug, Defendant began to receive adverse event reports with causal attributions, and its own employees published a study causally attributing the alleged risks to Beovu. (Compl. ¶¶ 54-59, 98-100 (citing Nguyen *et al.*, *supra*).) Despite this information, Defendant did not include warnings on its label about retinal vasculitis or retinal vascular occlusion until June 2020. (Compl. ¶ 74.) Thus, although Plaintiff does not expressly allege a change in type or increase in frequency or severity of Beovu's risks, the Court can infer from the

Complaint — construed in the light most favorable to Plaintiff, the non-movant — that Defendant had newly acquired information as defined by the CBE regulation.

Moreover, multiple federal courts — including those in cases with nearly identical complaints to the one here — have addressed the CBE regulation at issue in *Knight* and declined to dismiss failure-to-warn claims on preemption grounds, finding this argument more appropriate for summary judgment. *See*, *e.g.*, *Davison*, 2021 WL 4340412, at *4 (denying motion to dismiss in a nearly identical case involving Beovu, finding that "[a]lthough some issues of preemption may be [] purely legal questions . . . the underlying facts that drive those issues are not developed"); *Harris* Mem. & Order at 10-12 (No. 8-21cv32) (ECF No. 51) (finding that 27 post-approval, pre-exposure adverse event reports, as well as defendant-funded study demonstrating causal connection between ocular injuries and Beovu, constituted newly acquired information); *Mitchell v. Boehringer Ingelheim Pharms., Inc.*, 2017 WL 5617473, at *6 (W.D. Tenn. Nov. 21, 2017) (rejecting defendant's argument that post-approval adverse event reports must demonstrate an increase in severity or frequency of such events to constitute newly acquired information and denying motion to dismiss plaintiff's post-approval failure-to-warn claim); *see also Rayes*, 2022 WL 822195 (reversing dismissal of failure-to-warn claims involving Beovu, because plaintiff had sufficiently pled newly acquired information, including adverse event reports and "multiple cases of retinal vascular occlusion or retinal vasculitis in the clinic trials"); *Watler*, 2022 WL 971948, at *2-3 (in nearly identical case, denying motion to dismiss and finding that plaintiff sufficiently pled newly acquired information, including post-approval, pre-exposure adverse event reports with causal contributions, medical publications and Defendant's issuance of a safety signal).

The Court will follow these courts and find that Plaintiff has, at this point, sufficiently alleged that Defendant had newly acquired information that should have triggered a label change under the CBE regulation. Therefore, the Court will not dismiss Plaintiff's remaining failure-to-warn claim (Count Two) on preemption grounds.

3. Plaintiff pleads her fraud-based claims with sufficient particularity under Federal Rule of Civil Procedure 9(b).

Defendant further argues that Plaintiff fails to plead Count Three (Fraudulent Misrepresentation) and Count Four (Constructive Fraud) with sufficient particularity under Federal Rule of Civil Procedure 9(b). (Def.'s Mem. at 14.) According to Defendant, Plaintiff fails to allege "where or when [Defendant] made any alleged false statements to [P]laintiff, provide the exact substance of the alleged falsehoods, allege who made the statements, and explain what the alleged falsehoods caused her or her prescribing physician to do (or not do)." (Def.'s Mem. at 15.) Defendant also contends that Plaintiff identified neither the particular advertisements that contained misrepresentations, the safety statements that contained incorrect information, nor the timing of the statements. (Def.'s Mem. at 15-16.) Because Plaintiff makes only "generalized allegations," her fraud-based claims fail under Rule 9(b). (Def.'s Mem. at 16.) Plaintiff responds that she pleads her fraud-based claims with sufficient particularity. (Resp. at 22.) Plaintiff outlines various facts to support the particularity of her fraud-based claims regarding Defendant's misrepresentations to consumers, physicians and the public. (Resp. at 23-24.)

In Virginia, "[a] plaintiff asserting a cause of action for actual fraud bears the burden of proving by clear and convincing evidence the following elements: '(1) a false representation, (2) of a material fact, (3) made intentionally and knowingly, (4) with intent to mislead, (5) reliance by the party misled, and (6) resulting in damage to the party misled.'" *Richmond Metro. Auth. v.*

McDevitt St. Bovis, Inc., 507 S.E.2d 344, 346 (Va. 1998) (quoting *Evaluation Rsch. Corp. v. Alequin*, 439 S.E.2d 387, 390 (Va. 1994)). Similarly, "[c]onstructive fraud requires that a false representation of a material fact was made innocently or negligently, and the injured party was damaged as a result of reliance upon the misrepresentation." *Design & Prod., Inc. v. Am. Exhibitions, Inc.*, 820 F. Supp. 2d 727, 742 (E.D. Va. 2011) (citation omitted). Federal Rule of Civil Procedure 9(b) requires a party claiming fraud or mistake to "state with particularity the circumstances constituting fraud or mistake," though "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Although Rule 9(b) permits a plaintiff to plead the conditions of a person's mind generally, a plaintiff may not "evade the less rigid — though still operative — strictures of Rule 8." *Iqbal*, 556 U.S. at 687.

Ultimately, Rule 9(b) requires plaintiffs to plead with particularity "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999) (citations omitted). A plaintiff must also plead "reasonable, detrimental reliance . . . with particularity." *Xia Bi v. McAuliffe*, 927 F.3d 177, 184 (4th Cir. 2019) (citations omitted) (explaining that the rationale behind Rule 9(b)'s heightened pleading standard "applies with special force to allegations of reliance, which inherently rest on information within a plaintiff's possession"). Rule 9(b) seeks "to provide defendants with fair notice of claims against them and the factual ground upon which they are based." *McCauley v. Home Loan Inv. Bank, F.S.B.*, 710 F.3d 551, 559 (4th Cir. 2013). Thus, "lack of compliance with Rule 9(b)'s pleading requirements is treated as a failure to state a claim under Rule 12(b)(6)." *Harrison*, 176 F.3d at 783 n.5.

The Court finds that Plaintiff pleads her fraud-based claims — Counts Three and Four — with sufficient particularity. Plaintiff alleges that Defendant's publication reanalyzing the clinical trial data that it submitted to the FDA demonstrated that Defendant had failed to reveal the drug's significant vision-related risks to consumers, physicians and the public on Beovu's label. (Compl. ¶¶ 98-100.) Further, Plaintiff elaborates that she and her treating physicians relied on a number of Defendant's misrepresentations and omissions about the defects and dangers of Beovu, including:

- Defendant did not include in its label data that demonstrated that Beovu has a 2,312% increase in relative risk for retinal vasculitis or retinal vascular occlusion and related sequelae, and it stated that retinal vasculitis and retinal vascular occlusion occurred as 1% of clinical trial patients, but in fact, a minimum of 3.3% of patients actually suffered these injuries in Beovu clinical trials.

- Defendant failed to include or provide adequate warnings regarding the true risks of Beovu in the drug's label.

- Defendant did not issue a safety communication or update its product labeling after receiving post-marketing adverse event reports involving retinal vasculitis, uveitis and/or retinal vascular occlusion.

- Defendant issued press releases during March and April 2020 stating that adverse events related to Beovu remained consistent or below that listed on the FDA-approved label for Beovu — which, as discussed above, underreported these risks — thereby understating the vision-related risks of Beovu.

(Compl. ¶¶ 142(a)-(b), (d); 166(a)-(b), (d).)

To the extent that they apply to Beovu's product label, Plaintiff's allegations adequately alert Defendant of the claims against it, as Rule 9(b) requires. *See Rayes*, 2022 WL 822195, at *2 (holding that allegations that "Novartis stated that only 1% of patients experienced retinal vasculitis and retinal vascular occlusion in the clinical trials, but the real number was 3.3%," and that plaintiff and his physicians relied on the 1% figure, satisfied Rule 9(b)); *Watler*, 2022 WL

971948, *3 (denying motion to dismiss fraud-based claims under Rule 9(b) in nearly identical Beovu case); *Davison*, 2021 WL 4340412, at *4 (same); *Harris* Mem. & Order at 14-16 (No. 8:21cv32) (ECF No. 51) (same). These claims "specify the fraudulent statement, explain why the statement was fraudulent, and plausibly state that [Plaintiff's] physician[s] relied on the misreported data," and they can survive the instant Motion. *Rayes*, 2022 WL 822195, at *2.

However, Plaintiff's allegations that Defendant "encouraged ophthalmologists to switch their patients to Beovu" from safer alternatives and marketed Beovu to patients who had previously used VEGF inhibitors despite not adequately studying this population in clinical trials do not satisfy Rule 9(b). (Compl. ¶¶ 142(c), 166(c).) Unlike the allegations outlined above, which pertain to Beovu's label, these allegations do not identify the marketing or promotional materials that allegedly contain such misrepresentations and omissions. *Rayes*, 2022 WL 822195, at *2 (affirming dismissal of fraud-based claims in Beovu suit that did not concern Beovu's label and holding that the allegations regarding advertising that encouraged providers to switch their patients to Beovu did not properly specify "'how' [plaintiff] was defrauded"). For that reason, Plaintiff's fraud-based claims may proceed, but only as they relate to Beovu's label.

4. Plaintiff sufficiently pleads her claim for punitive damages.

Defendant asserts that Plaintiff's claim for punitive damages (Count Five) does not adequately allege willful and wanton conduct. (Def.'s Mem. at 16.) In particular, Defendant contends that the Complaint does not allege that Defendant "knew that any injury would result from [its misrepresentations and omissions regarding the risks of Beovu] or that [Defendant] acted with malice." (Def.'s Mem. at 17.) Plaintiff responds that her claim for punitive damages need only satisfy Rule 8 — a more lenient pleading standing than Rule 9(b), as discussed above

— and that she properly alleges that Defendant behaved intentionally and maliciously. (Resp. at 24-25.)

Punitive damages "are allowable only where there is misconduct or malice, or such recklessness or negligence as evinces a *conscious* disregard of the rights of others." *Baker v. Marcus*, 114 S.E.2d 617, 621 (Va. 1960). In other words, the plaintiff must show "the most egregious conduct." *Baker*, 883 F. Supp. 2d at 581 (quoting *Bowers v. Westvaco Corp.*, 419 S.E.2d 661 (Va. 1992)). To survive a motion to dismiss, a claim for punitive damages need not meet the stringent requirements of Rule 9(b); instead, it need only "contain[] sufficient factual matter which, accepted as true, 'state[s] a claim to relief that is plausible on its face.'" *Id.* (quoting *Ashcroft*, 556 U.S. at 663)). However, "[i]ll will and proof of actual malice are unnecessary; malice can be inferred from circumstances." *Peacock v. J.C. Penney Co.*, 764 F.2d 1012, 1015 (4th Cir. 1985).

Plaintiff adequately pleads her claim for punitive damages. Plaintiff alleges that "Defendant[has] intentionally misrepresented the clinical trial data for Beovu to FDA, healthcare providers, and the general public in order to mask the true risk of retinal vascular occlusion, retinal vasculitis, intraocular inflammation, and other severe eye injuries related to Beovu use." (Compl. ¶ 175.) She elaborates that Defendant concealed information demonstrating Beovu's 2,312% increase in relative risk for retinal vasculitis or retinal vascular occlusion, and that Defendant's marketing efforts encouraged healthcare providers to switch their patients from other anti-VEGF agents to Beovu despite not adequately studying Beovu's effects on this patient population, among other allegations. (Compl. ¶¶ 177-81.) Further, Plaintiff alleges that "Defendant['s] actions were willful and malicious in that Defendant['s]

conduct was carried on with a conscious disregard for the safety and rights of Plaintiff and others." (Compl. ¶ 182.)

Contrary to Defendant's assertion, Plaintiff need not allege that Defendant knew that injury would result from its misrepresentations and omissions. "Wilful (*sic*) or wanton conduct imports knowledge and consciousness that injury will result from the act done." *Wallen v. Allen*, 343 S.E.2d 73, 78 (Va. 1986) (emphasis removed). At this stage, Plaintiff alleges specific facts to show that Defendant behaved willfully and maliciously that enable the Court to infer its knowledge that injury would result. For these reasons, her punitive damage claim survives the instant Motion.

IV. CONCLUSION

For the reasons set forth above, the Court will grant in part and deny in part the Motion to Dismiss. Specifically, the Court will grant the Motion to Dismiss as to Count One and the portions of Plaintiff's fraud-based claims (Counts Three and Four) regarding Defendant's advertising that encouraged healthcare providers to switch their patients to Beovu. As it relates to all other claims, the Motion will be denied. Further, the Court will grant Plaintiff's and Defendant's Judicial Notice Requests.

An appropriate Order will issue.

Let the Clerk file a copy of this Memorandum Opinion electronically and notify all counsel of record.

/s/
David J. Novak
United States District Judge

Richmond, Virginia
Date: June 30, 2022