IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ROME DIVISION

Stephen Swinney,

Plaintiff,

Case No. 4:22-cv-90-MLB

v.

Mylan Pharmaceuticals, Inc., Viatris Specialty, LLC, and Viatris, Inc.,

Defendants.

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OPINION & ORDER

This is a product liability case. Plaintiff alleges Defendants manufactured a drug that caused his late wife to develop a blood clot that killed her. He asserts claims for strict liability, failure to warn, "failure to timely report adverse drug experiences," negligence, wrongful death, and "negligent omission to act when reasonable conduct required action." He also brings a derivative claim for punitive damages. Defendants move to dismiss, arguing Plaintiff's claims are preempted and that even if they were not, he fails to allege the required elements. (Dkts. 18, 18-1.) The Court grants Defendants' motion.

I. Background[1]

In April 2020, Megan Swinney (Plaintiff's wife) died from a blood clot after months of using a prescription birth control patch known as Xulane. (Dkt. 16 ¶¶ 6–9.) Defendant Mylan Pharmaceuticals manufactured and sold Xulane. (*Id.* at ¶¶ 8, 9.) Plaintiff says at some point Defendant Mylan changed its name or merged with Defendants Viatris, Inc. and Viatris Specialty, LL—making all Defendants jointly liable for the same conduct.

The drug Mrs. Swinney took had originally been manufactured and sold under the brand-name "Ortho Evra." (*Id.* ¶ 8.)[2] By the time Mrs. Swinney died, Ortho Evra's manufacturer had withdrawn the drug from the market because several women using the drug had developed blood clots. (*Id.*) After withdrawing the drug, the manufacturer also stopped collecting safety data or reporting any such data to the FDA. (*Id.*)

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[1] For purposes of resolving Defendants' motion to dismiss, the Court accepts the allegations of Plaintiff's complaint as true. *See Wooten v. Quicken Loans, Inc.*, 626 F.3d 1187, 1196 (11th Cir. 2010).

[2] As discussed in detail below, Plaintiff argues Xulane assumed brand-label status after Ortho Evra was withdrawn from the market. (Dkts. 16 ¶¶ 8, 21; 19-1 at 2.) The Court need not accept this legal conclusion as true. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Defendant Mylan knew the brand-named manufacturer had stopped recording and reporting negative safety information for Ortho Evra. (*Id.*)

Defendant Mylan continued manufacturing and selling Xulane but did not report negative safety information to either the FDA or the original manufacturer. (*Id.*) By the time Mrs. Swinney died, Defendants knew Xulane posed an extreme risk of blood clots in women—like Mrs. Swinney—with a body mass index of 30 kg/m^2 or more. (*Id.* ¶¶ 11–12.) Defendants did not disclose this risk on the Xulane label. Neither Ms. Swinney nor her doctors knew about the risk. (*Id.* ¶ 11.)

Plaintiff raises six claims: (1) Defendants are strictly liable because Xulane was not safe for preventing pregnancy in women with BMIs of 30 kg/m^2 or greater and Xulane's packaging was defective for failing to warn against this risk (*id.* ¶ 14–16); (2) Defendants—despite knowing of this risk—failed to warn Mrs. Swinney about it in violation of Georgia law (*id.* ¶¶ 17–20); (3) Defendants breached a duty to timely report adverse events related to Xulane to FDA (*id.* ¶¶ 21–26); (4) Defendants acted negligently by not conducting further testing and research to determine the safety of Xulane (*id.* ¶¶ 27–32); (5) Defendants acted negligently by not sharing their knowledge of adverse events related to Xulane with

FDA or Ortho Evra's manufacturer (*id.* ¶¶ 36–42); and (6) Defendants' wrongful actions caused Mrs. Swinney's death (*id.* ¶¶ 33–34). Plaintiff also brings a derivative claim for punitive damages. (*Id.* ¶ 35.)

II. Standard

A court may dismiss a claim if it fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). In deciding a motion to dismiss under Rule 12(b)(6), the Court must accept as true all well-pleaded, nonconclusory allegations. *Iqbal*, 556 U.S. at 678–80. But the Court need not "accept as true a legal conclusion couched as a factual allegation." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. 555). Put another way, a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* This so-called "plausibility standard" is not a probability requirement. But the plaintiff must allege enough facts so that it is reasonable to expect that discovery will lead to evidence supporting the claim. *Id.*

III. Discussion

Federal law draws important distinctions between brand-label and generic drugs. "[A] manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011). "Meeting these requirements involves costly and lengthy clinical testing." *Id.* Originally, this rule applied to all new drugs upon their introduction to the market. *See id.* Now, however, "'generic drugs' can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA." *Id.* (citing 21 U.S.C. § 355(j)(2)(A)). So, a "brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label," but a "manufacturer seeking generic drug approval . . . is responsible" only "for ensuring that its warning label is the same as the brand name's" warning label *Id.* at 613.

This distinction also governs updates to medication labeling after approval. In certain circumstances, brand-name manufacturers can revise their labeling unilaterally (that is, without prior FDA approval) to "add or strengthen a contraindication, warning, [or] precaution" through

a procedure called the "changes-being-effected" (CBE) process. *Id.* at 614 (discussing 24 C.F.R. § 314.70(c)(6)). In contrast, generic manufacturers can use the CBE process "*only* . . . to match an updated brand-name label or to follow the FDA's instructions." *Id.* at 2575 (emphasis added). So, "CBE changes unilaterally made to strengthen a generic drug's warning label . . . violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's." *Id.*

A. Preemption

Defendants say federal law preempts Plaintiff's claims. (Dkt. 18-1 at 9, 19.) They argue—and Plaintiff does not dispute—that all his claims are essentially premised on Defendants' supposed breach of their state-law duty to warn Plaintiff's wife of potential adverse effects from Xulane. (*Id.* at 9.) And because Defendants could not unilaterally alter Xulane's warning label, those claims are barred by the Supreme Court's decisions in two cases—*Mensing* and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). (*See id.* at 9, 19.)[3] Plaintiff acknowledges that "normally

[3] Defendants maintain that Plaintiff's negligent research and testing claim is really a failure-to-warn claim in disguise (and so is preempted). (Dkt. 18-1 at 19.) But even if it were not, they say, it still fails as a matter of law because "'Georgia does not recognize a cause of action for negligent testing.'" (*Id.* (quoting *Villegas v. Deere & Co.*, 135 F. App'x 279, 281

the [*Mensing*] line of cases dooms a failure to warn tort claim against the manufacturer of a generic medication." (Dkt. 19-1 at 2.) But, he says, his claim "presents a unique and distinguishable factual instance of first impression." (*Id.* at 3.)

1. *Mensing*

Plaintiff first argues that, because Ortho Evra was pulled from the market, Xulane has now assumed brand-label status. (Dkts. 16 ¶¶ 8, 21; 19-1 at 2.) So—according to Plaintiff—Defendants "incurred additional duties in relation to FDA reporting and under Georgia law to their consumers as a result of this shift." (Dkt. 19-1 at 2.) In his view, to satisfy these duties, Defendants had to "shar[e] negative outcome information with the FDA . . . and the manufacturer of Ortho Evra." (*Id.* at 3.)

Plaintiff is wrong and cites no authority for his allegation that, when a brand manufacturer leaves the market, a generic manufacturer must assume responsibility for label accuracy and adequacy. *Mensing*

(11th Cir. 2005).) Plaintiff does not respond to this argument, so the Court deems it unopposed. *See* L.R. 7.1(B), NDGa ("Failure to file a response shall indicate that there is no opposition to the motion."); *Top Sales & Servs., Inc. v. City of Forest Park*, 2010 WL 5068193, at *5 (N.D. Ga. Dec. 7, 2010) (treating as unopposed defendants' grounds for dismissal that plaintiffs did not address).

recognizes broad preemption. It preempts "claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturers." *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 391 (6th Cir. 2013). "[A]ny state-law claim involving a generic drug label or its warning is preempted and must be dismissed with prejudice under *Mensing*." *In re Accutane Prods. Liab. Litig.*, 2011 WL 6224546, at *2 (M.D. Fla. Nov. 9, 2011). This is because it is "impossible" for a generic-drug manufacturer to "comply with both [its purported] state-law duty to change the label and [its] federal-law duty to keep the label the same." *Mensing*, 564 U.S. at 618. "No matter the garb in which [a plaintiff] attempts to present them," claims that are "at bottom allegations regarding [a generic manufacturer's] failure to warn . . . cannot escape *Mensing*'s grasp." *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013).

Xulane is a generic drug and, as such, Defendants could not make any changes to its label without first receiving permission from FDA. Plaintiff's conclusory assertion that Xulane obtained brand-label status when Ortho Evra was withdrawn from the market is unsupported by any

authority.[4] But even if it was, Plaintiff does not allege Defendants gained the authority to unilaterally change Xulane's warning label. Indeed, Plaintiff implicitly concedes—regardless of Xulane's status—Defendants still cannot make changes to the drug's warning label on their own. While he says he needs discovery to determine "what rights and obligations Defendants have toward the FDA following the discontinuation of Ortho Evra," his entire theory of liability is that, with Ortho Evra off the market, "FDA would have allowed Defendants to suggest and submit *requests* to change the warning label." (Dkt. 16 ¶ 8

[4] Defendants say "FDA records confirm Ortho Evra is still the [reference listed drug]" for Xulane and that "Xulane is *not* the [reference listed drug]." (Dkt. 18-1 at 11–13 (emphasis in original).) In support, they cite FDA's website and the Orange Book (in which FDA lists patents to "facilitate the substitution of generic products for brand products"). *See Midlothian Labs., L.L.C. v. Pamlab, L.L.C.*, 509 F. Supp. 2d 1065, 1084 (M.D. Ala. 2007). Plaintiff objects to the authenticity of the website because he "is unaware of any statute or regulation that designates this website as the official source for such information . . . nor any statute or regulation that imposes a duty upon the FDA to ensure the website is complete, accurate, and up-to-date." (Dkt. 19-1 at 7.) Regardless of the website's (or the Orange Book's) authenticity, the Court does not consider them in reaching its decision because Defendants do not ask the Court to take judicial notice of the website or the Orange Book or otherwise meet their burden in showing the Court can consider them at this stage of the litigation. And in any event, whether Xulane is the reference listed drug does not matter to the Court's conclusion, which is based on Defendants' ability to unilaterally alter Xulane's label.

(emphasis added).)

Defendants' ability to change Xulane's label *without* permission from FDA is what matters. *See Mensing*, 564 U.S. at 623–24 ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance . . . that party cannot independently satisfy those state duties for pre-emption purposes."). Plaintiff all but admits Defendants cannot do so. His claims fail. *See Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1348 (N.D. Ga. 2012) (dismissing failure-to-warn claim where plaintiff had not shown that even if drug was designated as reference listed drug, manufacturer had "the right to use the CBE process to change labels").

As a second argument (an end-around this problem), Plaintiff says he also brings a negligent omission claim. (Dkt. 19-1 at 2–3.) He says his allegations raise an issue of first impression: "whether an additional duty is owed under Georgia law to the public by the manufacturer of a generic medication when it acquires the knowledge that the brand-manufacturer is no longer collecting or reporting safety data concerning the medication in question." (*Id.* at 3.) He says the answer is "yes," a generic manufacturer owes this duty to provide information when it

knows the brand manufacturer is not doing so. (*Id.*) But getting to this conclusion requires a long chain of inferences. Plaintiff suggests Defendants could have complied with both state and federal law by sharing information with FDA and Ortho Evra's manufacturer, which *may* have prompted a change to the Ortho Evra label and in turn *may* have resulted in a change to Xulane's label. (Dkt. 16 ¶ 39.) Then, this change *may* have caused Mrs. Swinney's doctors not to prescribe Xulane, which *might* have prevented her death. (*Id.*) Regardless of how Plaintiff labels his claims, his theory is precisely the sort of "Mouse Trap game" *Mensing* prohibits.

In *Mensing*, the plaintiffs argued the generic manufacturer defendants could have complied with both state and federal law if they "had asked the FDA for help in changing the corresponding brand-name label." 564 U.S. at 619. This, in turn, may have triggered a "Mouse Trap game that eventually led to a better label" on the generic drug. *Id.* But—like in *Mensing*—even if Defendants had taken the steps Plaintiff wants, they still could comply with federal law "if, and only if, the FDA and the brand-name manufacturer changed the brand-name label." *Id.* at 620. Plaintiff's claim is far from novel. It is—in all pertinent respects—

virtually the same as the one shot down by *Mensing*. Other courts agree. *See, e.g.*, *Morris v. PLIVA, Inc.*, 713 F.3d 774, 778 (5th Cir. 2013) (even if federal duty to ask for help existed, "state tort law 'did not instruct . . . [m]anufacturers to communicate with the FDA about the possibility of a safer label'") (citation omitted); *Jacobsen v. Wyeth, LLC*, 2012 WL 3575293, at *11 (E.D. La. Aug. 20, 2012) (holding "even if a duty to work toward label changes existed, the plaintiffs' claims were preempted nonetheless").

Plaintiff's theory conflates the purported duty—or even the ability—for Defendants to take steps to change the Xulane label with the duty to warn imposed by Georgia law. But Plaintiff identities no state law duty to report safety information or take other steps to change a product's label, whether independent or subsumed by the duty to warn. Nor could he. A manufacturer's failure to report adverse events to FDA is not a "traditional state-law tort claim[]" because it "seek[s] to enforce a duty owed to the FDA." *Frey v. Bayer Corp.*, 499 F. Supp. 3d 1283, 1288 (M.D. Ga. 2020) (internal quotation marks and citation omitted).

As for the *actual* duty imposed under Georgia law, merely taking steps—by submitting adverse event reports or otherwise—would not

have satisfied it. Plaintiff points to nothing in Georgia law suggesting that anything less than proving the label was inadequate would subject Defendants to liability. Indeed, the only way for a plaintiff to prove a failure-to-warn claim in Georgia is to show the manufacturer "(1) fail[ed] to adequately communicate the warning to the ultimate user or (2) fail[ed] to provide an adequate warning of the product's potential risks." *Thornton v. E.I. Du Pont De Nemours & Co., Inc.*, 22 F.3d 284, 289 (11th Cir. 1994). So, to hold Defendants liable, Plaintiff would have to prove that a stronger warning about the risk of blood clots would have prevented his wife's death. But it was impossible for Defendants to unilaterally amend its label to provide this warning. *Mensing* bars Plaintiff's claims. *See Mensing*, 564 U.S. at 619 (asking FDA for help "would have not satisfied [the manufacturers'] state tort-law duty to provide adequate labeling" because "[s]tate law demanded a safer label; it did not instruct the [m]anufacturers to communicate with the FDA about the possibility of a safer label").

2. *Buckman*

Defendants also say that Plaintiff's claims—in addition to being preempted by *Mensing*—are foreclosed by the Supreme Court's decision

in *Buckman* because his "theory of liability is premised on a failure to take steps" required by FDA "to advise FDA of alleged risks associated with Xulane." (Dkt. 18-1 at 19.) They say this is essentially a fraud-on-the-FDA claim, and *Buckman* makes clear that only FDA can punish and deter fraud against it. (*Id.*) Regarding his claim Defendants failed to comply with FDA's reporting regulations, Plaintiff says Defendants ignore "a long line of cases recognizing that such claims based on state tort law imposing a duty that parallels the FDA reporting requirements are not preempted." (Dkt. 19-1 at 4–5.) He argues his claims invoke duties under state law that run parallel with Defendants' duty to report to FDA. (*Id.* at 5.) Plaintiff is wrong again.

Buckman bars most claims challenging the adequacy of a manufacturer's disclosures to FDA because they "inevitably conflict with the FDA's responsibility to police fraud consistently with [its] judgment and objectives." 531 U.S. at 350. So, where a claim "exist[s] solely by virtue of the [Federal Food, Drug, and Cosmetic Act]," it fails under *Buckman*. *Id.* at 352–53. And the Eleventh Circuit has held—pursuant to *Buckman*—that claims like Plaintiff's (that is, those brought under a "failure-to-report" theory) are expressly prohibited absent an

independent, parallel state duty. *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (affirming dismissal of failure-to-report theory as preempted because manufacturer's "duty [wa]s owed to the FDA," not plaintiff, and plaintiff's "theory of liability [was] not one that state tort law traditionally occupied"). To that end, courts in Georgia consistently reject as preempted claims based only on the defendant's purported failure to comply with FDA reporting requirements. *See, e.g.*, *Williams v. St. Jude Medical, S.C., Inc.*, 2017 WL 11113322, at *9 (N.D. Ga. Oct. 19, 2017); *Connolly v. Sandoz Pharms. Corp.*, 2014 WL 12480025, at *5 (N.D. Ga. Dec. 23, 2014).

In arguing otherwise, Plaintiff says state law duties—like the one to use reasonable care or to disclose knowledge of a dangerous condition—can run parallel to federal obligations such that it is not impossible to comply with both. (Dkt. 19-1 at 5–6.) He points specifically to a narrow exception to *Buckman* allowing state law claims to move forward so long as they are not based on duties that are "different from, or in addition to" the requirements imposed by federal law. (*Id.* (citing *Barnes as Next Friend of Gibson v. Medtronic, Inc.*, 2021 WL 3742436 (N.D. Ga. Aug. 24, 2021).) This case does not fit that exception.

"'Parallel' state duties survive" preemption only if "they claim a violation of state tort law that aligns with a federal requirement." *Mink*, 860 F.3d at 1326 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008)). The Court already concluded Defendants' alleged wrongdoing (*i.e.*, not taking steps to change the Xulane label) does not violate state law.[5] So, there is no independent state duty at all—much less a parallel one. Plaintiff's claim, then, boils down to his allegation that Defendants violated FDA's reporting requirements. That fails under *Buckman*.

Plaintiff's claims are preempted by *Mensing* and *Buckman*, so they must be dismissed.

B. Failure to Plead Required Elements

Defendants say, even if Plaintiff's claims were not preempted, they still fail because he did not adequately plead their required elements.

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[5] And even if it did, it would have been impossible to comply with state law without violating federal law. There is no exception for parallel claims to the doctrine of impossibility preemption, which is grounded in the Supremacy Clause. *See Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476 (5th Cir. 2014) (where "the Supremacy Clause—not a statute—made it impossible for the generic defendant to do what state law required of it . . . the inquiry is not whether there is a 'parallel' claim where one looks for absence of a conflict with the statute; the inquiry is whether the state law claim is impliedly preempted").

(Dkt. 18-1 at 17.) They contend Plaintiff did not allege—as required by Georgia law—that Mrs. Swinney's doctors would have made a different decision had Defendants provided stronger warnings. (*Id.*) Plaintiff responds in conclusory fashion that "[u]nder general notice-pleading standards, Plaintiff has pled sufficient facts that should allow this case to proceed." (Dkt. 19-1 at 6.) Even if that were sufficient to respond to Defendants' arguments, Plaintiff did not adequately plead his failure-to warn claims.

As an initial matter, general notice pleading is not the standard in federal court. Rather, Plaintiff must meet the plausibility standard set forth in *Twombly* and *Iqbal*. *See Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. 555). He cannot meet that standard.

In failure-to-warn claims, Georgia recognizes the learned intermediary doctrine, "which alters the general rule that imposes liability on a manufacturer for failing to warn an end user of the known risks or hazards of its products." *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010). According to the doctrine, the "manufacturer of 'a prescription drug' . . . does not have a duty to warn the patient of the dangers involved with the product, but instead has a

duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.'" *Id.* (quoting *McCombs v. Synthes (U.S.A.)*, 587, S.E.2d 594, 594 (Ga. 2003)). To succeed, the plaintiff must show that, if the intermediary had "the information the plaintiff contends should have been provided," he or she would have taken a different course of action. *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002).

Plaintiff alleges Defendants were obligated to warn his wife about Xulane's purported dangers. (Dkt. 16 ¶¶ 18–19.) But the learned intermediary doctrine precludes such a duty. Plaintiff fails to allege that Defendants should have—but did not—warn Mrs. Swinney's *doctors* about Xulane's alleged risk. In fact, the complaint mentions her physicians only once, saying generally that she and "her physicians" were unaware of Xulane's risk for causing blood clots. (*Id.* ¶ 11.) Even if that were enough for Plaintiff to allege Defendants owed a duty to inform his wife's doctors, Plaintiff does not allege that—had the doctors known about Xulane's purported risks—they would have chosen a different course of action. Nor does he say anything about what alternate warning Defendants should have given. Without such allegations, Plaintiff's

claims fail. *See Tutwiler v. Sandoz, Inc.*, 726 F. App'x 753, 756–57 (11th Cir. 2018) (affirming dismissal where plaintiff did not allege learned intermediary would have changed intermediary's prescribing decision had he received a better warning).[6]

IV. Conclusion

The Court **GRANTS** Defendant's Motion to Dismiss Plaintiff's First Amended Complaint (Dkt. 18).

SO ORDERED this 17th day of February, 2023.

MICHAEL L. BROWN
UNITED STATES DISTRICT JUDGE

[6] Defendants say Plaintiff's punitive damages claim is derivative of his primary claims, and so must also fail. (Dkt. 18-1 at 22.) Plaintiff does not respond to this argument, so the Court deems it unopposed. *See* L.R. 7.1(B), NDGa; *Top Sales & Servs.*, 2010 WL 5068193, at *5. Even if Plaintiff had responded, Defendants are right. *See Lyons v. Boehringer Ingelheim Pharms., Inc.*, 491 F. Supp. 3d 1350, 1368 (N.D. Ga. 2020) (dismissing derivative claims where primary claims failed).