FILED
2018 Mar-20 PM 02:32
U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

PHILLIP McGEE, SR.,	]	
	]	
Plaintiff,	]	
	]	
v.	]	**CIVIL ACTION NO.**
	]	**4:16-CV-2082-KOB**
BOEHRINGER INGELHEIM	]	
PHARMACEUTICALS, INC.,	]	
	]	
Defendant.	]	

MEMORANDUM OPINION

Plaintiff Phillip McGee brings this products-liability suit against Boehringer Ingelheim Pharmaceuticals, Inc.; he alleges that "Jardiance," a prescription drug manufactured and sold by Boehringer, caused him to go into diabetic ketoacidosis ("DKA"). Mr. McGee, a Type-II diabetic, asserts, essentially, that Boehringer failed to adequately warn him that Jardiance presented a known risk of DKA.

The matter comes before the court on Boehringer's motion to dismiss Mr. McGee's First Amended Complaint under Fed. R. Civ. P. 12(b)(6). (Doc. 24). Boehringer contends that federal law preempts Mr. McGee's claims and that the complaint fails to provide a sufficient factual basis to state a claim for relief.

For the reasons discussed below, the court will GRANT Boehringer's motion to dismiss.

First, the court will GRANT Boehringer's motion to the extent Mr. McGee attempts to raise a claim that Boehringer should have told the FDA about Jardiance's DKA risk during the drug's approval process. Federal laws and regulations preempt such a claim, and the court will DISMISS any such claim WITH PREJUDICE.

Second, the court will GRANT Boehringer's motion to dismiss as to Mr. McGee's claim that Boehringer should have updated Jardiance's label to warn about DKA *after* the FDA approved Jardiance and *before* Mr. McGee's injuries. In the complaint, Mr. McGee fails to allege whether the body of relevant newly-available information increased during this specific time period. The court will therefore DISMISS Mr. McGee's failure-to-warn claims for this time period WITHOUT PREJUDICE.

Finally, Boehringer raises several other arguments in favor of dismissal. It argues that the learned intermediary doctrine bars Mr. McGee's failure-to-warn claims and that the complaint merely contains legal conclusions without factual underpinnings. Because the court will dismiss Mr. McGee's complaint without prejudice on the preemption issue, the court need not address these arguments at this time. As to these arguments, Boehringer's motion to dismiss is MOOT.

STANDARD OF REVIEW

A Rule 12(b)(6) motion to dismiss attacks the legal sufficiency of the complaint. Generally, the Federal Rules of Civil Procedure require only that the complaint provide "'a short and plain statement of the claim' that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957) (quoting Fed. R. Civ. P. 8(a)). A plaintiff must provide the grounds of his entitlement, but Rule 8 generally does not require "detailed factual allegations." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley*, 355 U.S. at 47). It does, however, "demand[ ] more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal* 556 U.S. 662, 678 (2009). Pleadings that contain nothing more than "a formulaic recitation of the elements of a cause of action" do not meet Rule 8 standards nor do pleadings suffice that are based merely

upon "labels or conclusions" or "naked assertions" without supporting factual allegations. *Twombly*, 550 U.S. at 555, 557.

The Supreme Court explained that "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting and explaining its decision in *Twombly*, 550 U.S. at 570). To be plausible on its face, the claim must contain enough facts that "allow[ ] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

FACTS

Boehringer sells Jardiance as a prescription drug designed to treat Type-II diabetes. Jardiance belongs to a class of drugs known as "SGLT-2 inhibitors" that, working properly, lowers patients' blood-glucose levels. The FDA approved Jardiance for use in treating Type-II diabetes on August 1, 2014. At that time, the FDA-approved label for Jardiance did not include warnings about DKA, a medical condition that rarely occurs in Type-II diabetics.

The FDA has a publicly-available database known as the Adverse Event Reporting System ("FAERS"). Beginning in March 2013, FAERS recorded "adverse events" in which Type-II diabetics on SGLT-2 inhibitors were hospitalized after going into DKA.

Mr. McGee is one such Type-II diabetic. In January 2015,[1] a doctor prescribed Jardiance to Mr. McGee as a treatment for his diabetes. On January 17, Mr. McGee went into DKA. Mr. McGee remained hospitalized until January 21. Mr. McGee had taken Jardiance from the time

[1] The complaint says Mr. McGee began taking Jardiance "in or about JanuaryMarch [sic] 2015." The court has read this apparent typographical error to mean "January 2015" because that is the most plausible date given the context of the complaint, which indicates Mr. McGee suffered the alleged injuries in January 2015 after taking Jardiance.

his doctor prescribed it until his hospitalization. Mr. McGee asserts that he would not have taken Jardiance if Boehringer had disclosed the risk of DKA when taking the drug.

On May 15, 2015, several months after Mr. McGee's injury, the FDA issued a general warning that SGLT-2 inhibitors like Jardiance carried a risk of DKA. To support that warning, the FDA cited cumulative FAERS data between March 2013 and June 2014.

And, on December 4, 2015, the FDA issued an additional warning about DKA and SGLT-2 inhibitors, citing cumulative FAERS data between March 2013 and May 2015. Mr. McGee alleges that the data included 73 hospitalizations related to SGLT-2 inhibitors and DKA, with "more than 50 additional adverse events collected after June 6, 2014."

At the same time the FDA issued the additional warning based on the cumulative data in December 2015, it updated the label for Jardiance and other SGLT-2 inhibitors to include a warning "about the risks of too much acid in the blood." (Doc. 19 ¶ 40). The warning told patients to stop taking the drug and to seek medical attention if they displayed any DKA symptoms. In addition, the FDA required SGLT-2 inhibitor manufacturers to conduct a study to analyze reports of DKA patients treated with SGLT-2 inhibitors over a five-year period.

In this lawsuit, Mr. McGee contends that Boehringer should have been aware that Jardiance posed a DKA risk based on the FAERS data collected between March 2013 and June 2014. (Doc. 19 ¶¶ 54-55). Furthermore, Mr. McGee contends, Boehringer also had access to the additional data collected after June 2014. Mr. McGee thus asserts that Boehringer should have amended Jardiance's label through the FDA's "Changes Being Effected" process, which permits manufacturers like Boehringer to add warnings to FDA-approved labels when the manufacturer has newly-available information to support the warning.

Mr. McGee breaks his allegations into three counts. In Count I, Mr. McGee alleges that Boehringer violated the Alabama Extended Manufacturer's Liability Doctrine. In the AEMLD claim, Mr. McGee focuses on Boehringer's failure to warn him and his physician about the risk of DKA, alleging that Boehringer "negligently and recklessly labeled, distributed, and promoted" Jardiance. (Doc. 19 at ¶ 82). In Count II, Mr. McGee in essence asserts that Boehringer negligently breached its duty of care by selling an SGLT-2 inhibitor with a known risk of DKA and by failing to warn that Jardiance could send a Type-II diabetic into DKA.[2] In Count III, Mr. McGee accuses Boehringer of gross negligence on the same failure-to-warn premises.

Mr. McGee asks for compensatory damages, medical expenses, damages for his pain and suffering, damages because he has an increased future risk of complications, punitive damages, interest, and attorneys' fees and costs.

DISCUSSION

Boehringer asserts that Mr. McGee cannot prevail because federal laws and regulations preempt his claims. Specifically, Boehringer says that it could not have issued a label any different than the label approved by the FDA for Jardiance and that, if it had done so, it would have violated federal law; that is, Boehringer could not have possibly complied with both federal law and Mr. McGee's expectations under state law at the same time. The Supremacy Clause of the Constitution preempts "state laws that require a private party to violate federal law." *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

[2] Mr. McGee's claim in Count II also includes "shotgun" claims that Boehringer breached a duty of care in everything from designing Jardiance to testing and delivering it. (*See* Doc. 19 ¶ 104). As discussed below, the court finds all of those "shotgun" claims insufficiently pled.

This case pits Mr. McGee's claims that Boehringer had a state-law duty to add a DKA warning to Jardiance's label against Boehringer's federal obligation to get FDA approval for changes to Jardiance's label.

At the federal level, the FDA regulates the manufacture, use, and sale of drugs. *Bartlett*, 133 S. Ct. at 2470-71. Before the FDA permits a manufacturer to sell a new drug, the manufacturer must submit a new drug application and demonstrate that its drug is safe and effective. *See* 21 U.S.C. § 355(b)(1)(A), (d).

Alongside that application, the manufacturer must submit proposed labeling for the new drug. *Bartlett*, 133 S. Ct. at 2471. The FDA must approve the label's exact text before the manufacturer can sell the new drug. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). Approved labeling includes, for example, a "Warnings and Precautions" section that describes potential hazards and risks as well as steps that patients should take if bad reactions occur. *See* 21 C.F.R. § 201.57(c)(6)(i). Similarly, an "Adverse Reactions" section describes "the overall adverse reaction profile of the drug based on the entire safety database." *Id.* § 201.57(c)(7). Although the FDA approves the label, "the manufacturer bears responsibility for the content of its label at all times." *Wyeth*, 555 U.S. at 570-71.

Generally, once the FDA approves the new drug, the manufacturer may only change the label after the FDA approves a supplemental application. *Wyeth*, 555 U.S. at 568. However, the manufacturer may use the "Changes Being Effected" ("CBE") process to add or strengthen warnings and precautions before the FDA approves the supplemental application. *Id.*; *see also* 21 C.F.R. § 314.70(c)(6)(iii)(A).

A manufacturer may only use the CBE process if it has "newly acquired information," such as reports of adverse events or new analyses of old data. 21 C.F.R. §§ 314.70(c)(6)(iii),

314.3(b). In addition, the newly acquired information must show "reasonable evidence of a causal association" between the serious hazard and the drug. *See, e.g.*, 21 C.F.R § 201.57(c)(6)(i).

The FDA's drug-labelling regulations do not preempt a state duty when a plaintiff can show that the manufacturer had or should have had newly-acquired information that it could and should have used to modify its label to comply with state-law expectations. *Wyeth*, 555 U.S. at 573. In these circumstances, the pharmaceutical company "could independently do under federal law what state law requires of it." *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) (observing that manufacturers of generic drugs have different federal obligations than manufacturers of new drugs such that the preemption analyses for those manufacturers differ); *Wyeth*, 555 U.S. at 573.

So, if a plaintiff can allege the existence of newly-acquired information that supports a labeling change under the CBE regulation, and if the manufacturer subsequently fails to show by "clear evidence" that the FDA would not have approved a change to the label, then a failure-to-warn claim will survive the manufacturer's preemption defense. *Wyeth*, 555 U.S. at 573.

Further, to reject a preemption defense at the motion to dismiss stage, the court need only conclude that allegations contained in the complaint—taken as true and all inferences drawn in the plaintiff's favor—evade preemption as a matter of law. *See Quiller v. Barclays American/Credit, Inc.*, 727 F.2d 1067, 1069 (11th Cir. 1984). Here, the court recognizes that Boehringer theoretically could have complied with both its federal obligations and Mr. McGee's alleged state obligations so long as the state obligations are limited to the actions that Boehringer could and should have taken *after* Jardiance's approval and *before* Mr. McGee's injury. *See Wyeth*, 555 U.S. at 573. But Mr. McGee lumps together claims and facts from before, during,

and after this brief time period. Without clarification, the court cannot tell when Mr. McGee alleges Boehringer had what information.

To the extent Mr. McGee asserts that Boehringer should have alerted the FDA about Jardiance's DKA risk *before* Jardiance's approval, the claim is preempted because the claim is essentially one of failure to communicate with the FDA. Federal law preempts state-law claims based on a defendant's failure to communicate with the FDA. *See Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 348-51 (2001). As the Supreme Court observed, the FDA "has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud" and "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the [FDA] neither wants nor needs[.]" *Id.*; *see also PLIVA, Inc.*, 564 U.S. at 619. And common sense dictates that any information Boehringer obtained after January 17, 2015, when Mr. McGee suffered DKA, is irrelevant to Mr. McGee's claims because Boehringer could not have used that information to change its label and prevent Mr. McGee's injury from occurring.

In theory, Mr. McGee may be able to allege a non-preempted claim that Boehringer should have used the CBE process to modify Jardiance's label after its approval and before his injury. *See Wyeth*, 555 U.S. at 573 ("The CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited such a change."). But, the complaint makes no allegations about the data as it existed during the relevant time period before he had DKA. Rather, Mr. McGee broadly alleges that the FAERS database contained data about many DKA incidents that

occurred between March 2013 (before Jardiance's approval) and May 2015 (after his injury). And although Mr. McGee alleges that the body of data available to Boehringer regarding DKA incidents and SGLT-2 inhibitors increased from March 2013 through May 2015, he does not allege, for example, that the FAERS database collected any *new* DKA incidents after August 1, 2014—the date the FDA approved Jardiance— and before January 17, 2015—the date Mr. McGee suffered his injury. (*See* doc. 19 ¶¶ 38-39).

In his response to Boehringer's motion to dismiss, Mr. McGee claims that "two-thirds of the very data FDA used to require a label change and nearly two and a half times the reports that led to FDA issuing its May 15, 2015 warning were available to [Boehringer] after Jardiance['s] approval and before [Mr. McGee's] harm." (Doc. 28 at 5-6). But that allegation is not in the complaint, so the court cannot consider it to save the complaint. *Cf. GeorgiaCarry.Org v. Georgia*, 687 F.3d 1244, 1258 n.26 (11th Cir. 2012) ("[A] plaintiff may not amend the complaint through argument at the summary judgment phase of proceedings."). And Mr. McGee still fails to specify whether any *new* DKA adverse events occurred after Jardiance's approval and before Mr. McGee's harm. As it stands, the complaint at best contains ambiguity about the newly-available data that Boehringer had or should have had after Jardiance's approval and before Mr. McGee's injury.

As a final issue, the court cannot ignore that Mr. McGee's complaint is rife with shotgun allegations. The complaint buries itself in contentions like those in paragraph 75, which unhelpfully observes that Boehringer "has engaged in the business of designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling, testing, and/or distribution of" Jardiance, or paragraph 76, which purports to add that Boehringer "researched, developed,

designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released" Jardiance. (*See, e.g.*, doc. 19 ¶¶ 75-76).

Even more problematic is Count II of the complaint, which generally alleges negligence based on Boehringer's failure to warn. But, in Count II, Mr. McGee attempts to bring other negligence claims for conduct beyond Boehringer's failure to warn about Jardiance's risk of DKA. In paragraph 104, Mr. McGee alleges that Boehringer

> breached its duty of reasonable care and failed to exercise ordinary care in the research, development, *marketing*, supplying, promotion, *marketing*, advertisement, packaging, *sale*, testing, quality assurance, quality control, *sale*, and distribution [of Jardiance].

(Doc. 19 ¶ 104) (emphases added). Mr. McGee believes that his negligence claims "includ[e]" and are "not limited to" the allegations presented in paragraph 104. (Doc. 28 at 26). Paragraph 104, however, contains nothing but a useless set of legal conclusions.

Worse, the complaint spews these legal conclusions with few supporting facts that would assist Boehringer in understanding what Mr. McGee claims the company did wrong. This type of "shotgun" pleading fails to plead a cognizable cause of action. *See Weiland v. Palm Beach County Sheriff's Office*, 792 F.3d 1313, 1321-23 (11th Cir. 2015) ("The unifying characteristic of all types of shotgun pleadings is that they fail to one degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests."). If Mr. McGee chooses to file an amended complaint, he must eliminate the unnecessary and unhelpful "shotgun" assertions and claims. Fed. R. Civ. P. 8(a)(2).

CONCLUSION

The court will GRANT Boehringer's motion to dismiss. Any claim that Mr. McGee brings asserting that Boehringer should have told the FDA about Jardiance's DKA risk during

the drug's approval process is DISMISSED WITH PREJUDICE. As to the time period between the FDA's approval of Jardiance and before Mr. McGee's DKA incident, the court DISMISSES WITHOUT PREJUDICE Mr. McGee's failure to warn claims in Counts I, II, and III. The remaining grounds that Boehringer asserts for dismissal are MOOT.

Mr. McGee may file an amended complaint by April 4, 2018. If he chooses to file an amended complaint, Mr. McGee must, in addition to clarifying his allegations about the type and quantity of newly-available information, clean up the complaint by eliminating his "shotgun" claims and assertions.

The court will enter a separate Order consistent with this Memorandum Opinion.

DONE and **ORDERED** this 20th day of March, 2018.

Karon O. Bowdre

KARON OWEN BOWDRE
CHIEF UNITED STATES DISTRICT JUDGE