IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
EASTERN DIVISION

MELISSA MITCHELL,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No: 1:16-cv-02384-STA-egb
	)	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

ORDER PARTIALLY GRANTING AND PARTIALLY DENYING DEFENDANT'S MOTION TO DISMISS

Plaintiff Melissa Mitchell filed this product liability action under the Tennessee Product Liability Act ("TPLA"), Tenn. Code Ann. § 29-28-101 *et seq.*, against Eli Lilly and Company and Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), alleging that she developed diabetic ketoacidosis ("DKA") after she began taking Jardiance, a prescription medication approved by the Food and Drug Administration ("FDA") as safe and effective for the treatment of type 2 diabetes. Defendant BIPI holds the New Drug Application ("NDA") for Jardiance and co-markets the product with Eli Lilly and Company.[1] Jurisdiction is predicated on diversity of citizenship, 28 U.S.C. § 1332. Defendant BIPI has filed a motion to dismiss Plaintiff's second amended complaint. (ECF No. 62.) Plaintiff has filed a response to the motion (ECF No. 64), and Defendant has filed a reply to the response. (ECF No. 65.) For the reasons set forth below, Defendant's motion is **PARTIALLY GRANTED** and **PARTIALLY DENIED**.

[1] Defendant Eli Lilly was dismissed from this matter with prejudice on February 15, 2017. (ECF No. 58.)

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the complaint. *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1134 (6th Cir. 1996). Under Federal Rule of Civil Procedure 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." The Supreme Court clarified the pleading standard in *Bell Atlantic Corporation v. Twombly*, 550 U.S. 555 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Under *Twombly*, to survive a motion to dismiss, a complaint need not contain "detailed factual allegations," but it must contain more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action ..." 550 U.S. at 570. A complaint does not "suffice if it tenders 'naked assertions' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557). "[A] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556).

The plausibility standard "does not impose a probability requirement at the pleading stage; it simply calls for enough facts 'to raise a reasonable expectation that discovery will reveal evidence of illegal [conduct].'" *Twombly*, 550 U.S. at 556. In deciding whether the plaintiff has set forth a plausible claim, the Court must accept the factual allegations in the complaint as true. *Id.*; *see also Erickson v. Pardus*, 551 U.S. 89 (2007). This presumption, however, is not applicable to legal conclusions. *Iqbal*, 556 U.S. at 678. Therefore, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555).

"A court considering a 12(b)(6) motion may consider materials in addition to the complaint if such are public records." *Rodney v. LaHood*, 359 F. App'x 634, 637 (6th Cir. 2010). FDA documents may properly be considered on a motion to dismiss. *See*, *e.g.*, *Spier v. Coloplast Corp.*, 121 F. Supp. 3d 809, 811 n. 2 (E.D. Tenn. 2015) (taking judicial notice of "various publicly available" FDA documents).

Plaintiff's second amended complaint (ECF No. 56) alleges that Jardiance (empagliflozin) was approved by the FDA on August 1, 2014, as safe and effective for the treatment of type 2 diabetes. (SAC ¶ 15, ECF No. 56.) It is the third member of the newest class of medications used to treat type 2 diabetes known as sodium-glucose co-transporter 2 ("SGLT2") inhibitors. (*Id.*) The second amended complaint further alleges that Plaintiff began taking Jardiance to treat her diabetes in or about February 2015 and used Jardiance consistently until June 2, 2015. (*Id.* ¶¶ 26, 33.)

"On May 15, 2015, the FDA issued a safety alert covering the SGLT-2 inhibitor class, warning about the risk of DKA." (*Id.* ¶ 35.) The data on which the May 15, 2015, safety alert was premised "was collected from March 2013 to June 6, 2014, nearly two months prior to Jardiance's approval" and came from the FDA Adverse Event Reporting System ("FAERS"), "a publicly available database." (*Id.* ¶¶ 36-37.) "As part of its continued evaluation, on December 4, 2015[,] the FDA issued a new safety communication disclosing they had found 73 adverse events reported between March 2013 and May 2015 that required hospitalization due to ketoacidosis related to SGLT-2 inhibitors." (*Id.* ¶ 38.)

Plaintiff contends that Defendant BIPI "did not warn about the risks of DKA" at the time "JARDIANCE was approved" (*id.* ¶ 53) and did not "amend the label or utilize the [FDA's Changes Being Effected ('CBE')] process" to warn about the risks of DKA before Plaintiff used

the medication (*id.* ¶ 68(c)). She alleges that she was injured as a result of taking the drug without being warned of the possible risks. In addition to developing DKA, Plaintiff alleges that she experienced "other related health complications." (Id. ¶¶ 90, 114.)

According to Plaintiff, Jardiance's warnings were defective and/or unreasonably dangerous with regard to the increased risk of exposure to DKA because there were no warnings for DKA at any time prior to Plaintiff's alleged injury on June 2, 2015, and no DKA warning at any time prior to the December 4, 2015, label change. (*Id.* ¶¶ 54-56.)

Defendant contends that Plaintiff's failure-to-warn theory is premised solely on adverse events that occurred before Defendant received FDA approval for Jardiance. Defendant argues that any state law duty under the TPLA to provide a different warning at the time of Jardiance's FDA approval is preempted because, pursuant to federal regulations and Supreme Court precedent, the FDA assessed the warning at the time of approval, deemed Jardiance to be safe and effective when accompanied by that warning, and required Jardiance to be accompanied by the warning approved by the FDA at the commencement of marketing Jardiance. Accordingly, Defendant argues that both Plaintiff's strict liability and negligence claims, predicated on a failure-to-warn theory, are preempted by federal law. Defendant also argues that, even if Plaintiff's failure-to-warn theory is not preempted, she has not plausibly alleged how the Jardiance label was defective or unreasonably dangerous or how the alleged defect in the Jardiance label caused her injuries.

As this Court has previously noted,

> [t]he TPLA governs products liability actions in Tennessee and defines "product liability action[s]" as "all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packing, or labeling of any product." The TPLA also encompasses several different theories of products liability: "strict liability in tort;

> negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent or innocent; or under any other substantive legal theory in tort or contract whatsoever."

Strayhorn v. Wyeth Pharm., Inc., 887 F. Supp.2d 799, 813 (W.D. Tenn. 2012) (internal footnotes omitted). To maintain a claim under the TPLA, regardless of the theory of recovery, "the plaintiff must show that: (1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product." *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008). *See also* Tenn. Code Ann. § 29-28-105(a) (providing that, under the TPLA, a plaintiff may recover for injuries caused by a product that was "in a defective condition or unreasonably dangerous at the time [the product] left the control of the manufacturer or seller").

Under Tennessee law, "[m]anufacturers of prescription drugs . . . have a duty to market and distribute their products in a way that minimizes the risk or danger . . . [and] may discharge their duty by distributing the drugs with proper directions and adequate warnings;" adequate warnings are defined as those that "contain a full and complete disclosure of the potential adverse reactions to the drug." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428-29 (Tenn. 1994). "To plead a 'failure to warn' claim, Plaintiff must allege facts for the Court to infer that the Device was 'unreasonably dangerous' within the meaning of T.C.A. § 29–28–102(8)." *Maness v. Boston Sci.*, 751 F. Supp. 2d 962, 970 (E.D. Tenn. 2010) (footnote omitted).

As noted by Defendant, the FDA has the sole authority to approve prescription drugs for sale in the United States, and the Federal Food, Drug, and Cosmetic Act requires drug manufacturers to gain FDA approval before marketing or selling a new drug in interstate commerce. 21 U.S.C. § 355(a). To receive approval, the drug must "meet[] the statutory

standards for safety and effectiveness, manufacturing and controls, and labeling," as determined by the FDA. 21 C.F.R. § 314.105(c) ("[The] FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards.") The NDA or sNDA[2] must include "the labeling proposed to be used" for the drug, 21 U.S.C. § 355(b)(1)(F), 21 C.F.R. § 314.50(c)(2)(i), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling." 21 C.F.R. § 314.50(d)(5)(viii). The NDA or sNDA must also include "[t]he proposed text of the labeling . . . with annotations to the information in the [application] that support the inclusion of each statement . . . ." *Id.* § 314.50(c)(2)(i). To approve an NDA or sNDA, the FDA must determine, "based on a fair evaluation of all material facts," that the proposed label is not "false or misleading in any particular," 21 U.S.C. § 355(d)(7), or otherwise "does not comply with the requirements for labels and labeling." 21 C.F.R. § 314.125(b)(6)-(8). Once the FDA has approved an NDA or sNDA, the manufacturer must use the FDA-approved label. 21 U.S.C. §§ 331(c), 333(a), 352(a), (c).

After the FDA approves a drug, there are two ways a manufacturer can change the drug's label. "First, the default rule is that a manufacturer must secure FDA approval for a proposed change prior to distributing the product with the changed label." *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 37 (1st Cir. 2015) (citation omitted). Second, a drug manufacturer can, without prior FDA approval, make certain types of changes to the drug's label

[2] An NDA or sNDA (supplemental new drug application) consists of a compilation of materials that includes "full reports of [all clinical] investigations," 21 U.S.C. § 355(b)(1)(A); 21 C.F.R. § 314.50(d)(5), relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product . . . ." 21 C.F.R. § 314.50(d)(2), (d)(5)(iv).

by sending a "supplement submission" to the FDA pursuant to the CBE process.[3] 21 C.F.R. § 314.70(c)(6)(iii).

To use the CBE process, the drug manufacturer must satisfy two requirements. First, the label change must reflect "newly acquired information." *Id.* "Newly acquired information" is defined as "data, analyses, or other information not previously submitted to the Agency, which may include (but are 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(b). Second, the label change must be for the purpose of accomplishing at least one of five objectives, including "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling . . . ." 21 C.F.R. § 314.70(c)(6)(iii)(A).

In the present case, any claim that Plaintiff has made against Defendant based on the alleged inadequacy of the initial FDA approved label fails as a matter of law because Defendant was required to use that label when it first marketed Jardiance and could not have changed the label after FDA approval based on alleged pre-launch data that was known to the FDA at the time of the approval. *See In re Celexa*, 779 F.3d at 43 (affirming dismissal of complaint because defendants could not have independently changed drug label at time of FDA approval). *See also*

[3] The CBE process permits drug manufacturers to "add or strengthen a contraindication, warning, [or] precaution," 21 C.F.R. § 314.70(c)(6)(iii)(A) (2006), or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," C.F.R. § 314.70(c)(6)(iii)(C). When making labeling changes using the CBE process, drug manufacturers need not wait for preapproval by the FDA. *Wyeth*, 555 U.S. at 568. They need only simultaneously file a supplemental application with the FDA. 21 C.F.R. § 314.70(c)(6).

Utts v. Bristol–Myers Squibb Co., 26 F. Supp. 3d 66 (S.D.N.Y. 2016) (holding that failure-to-warn claims were preempted when claims were premised on adequacy of the label as approved by FDA when drug was first marketed and when plaintiffs did not plead "newly acquired information" that would have allowed the manufacturer to independently change drug label to add or improve warnings pursuant to CBE process); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 185 F. Supp. 3d 761, 769-70 (D.S.C. 2016) (finding that, because "the FDA approved the Lipitor label" and "specifically approved [a particular] statement," federal law preempted the "claim [that] Lipitor's label should have included different statements").

The FDA approves a drug only if it determines that the drug in question is safe for use under its proposed labeling and that the drug's probable therapeutic benefits outweigh its risks of harm. 21 U.S.C. § 355(d). "The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). In the present case, in approving Jardiance, the FDA instructed Defendant BIPI that "[c]ontent of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient package insert)." (Def's Exh. 1, Jardiance NDA Approval Letter, ECF No. 62-2). Thus, Jardiance would have been misbranded if, upon approval, Defendant had marketed Jardiance with labeling other than what the FDA approved in that *Wyeth* drew a line that "lets the FDA be the exclusive judge of safety and efficacy based on information available at the commencement of marketing, while allowing the states to reach contrary conclusions when new information not considered by the FDA develops." *In re Celexa*, 779 F.3d at 41.

Accordingly, Plaintiff's allegation that Jardiance was unreasonably dangerous because of its labeling at the time it was first marketed on August 1, 2014, and the allegation that BIPI

should have provided a different label that included a DKA warning on August 1, 2014, is preempted by federal law.

Additionally, to the extent that Plaintiff failed to respond to Defendant's argument that federal law prohibited it from changing the Jardiance label prior to or at the time of FDA's approval to market the drug, Plaintiff has waived that claim. *See Stewart v. City of Memphis*, 2017 WL 627467 at *9 (W.D. Tenn. Feb. 15, 2017) (finding that the plaintiffs' failure to address a portion of the motion to dismiss in the response constitutes a waiver of "any argument against the dismissal of these claims").

In addition to the pre-approval adverse information, Plaintiff has also alleged that Defendant was in possession of "'newly acquired information' such that [it] could, pursuant to the CBE regulation, act independently of the FDA to update" the Jardiance label with a DKA warning after the FDA approved Jardiance. As explained in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), "When making labeling changes using the CBE process, drug manufacturers need not wait for preapproval by the FDA, which ordinarily is necessary to change a label. They need only simultaneously file a supplemental application with the FDA." 564 U.S. at 614 (some citations omitted). *See also Wyeth*, 555 U.S. at 572-73 (rejecting a manufacturer's preemption defense and reasoning that, after receiving FDA approval for the drug, the manufacturer could have used the CBE process to update the drug's label when the risks alleged by the plaintiff became apparent).

In determining whether Plaintiff has adequately pled a claim that Defendant should have used the CBE to change the Jardiance label after its FDA approval, Plaintiff cannot rely on the twenty cases of DKA reported in the FAERS database prior to Jardiance's approval because those cases do not constitute newly acquired information that was unknown to the FDA at the

time of FDA approval. Instead, to survive Defendant's motion to dismiss, Plaintiff must allege the existence of information that was unknown to the FDA prior to label approval such that Defendant should have changed Jardiance's label through the CBE process. *See In re Celexa*, 779 F.3d at 42-43 (affirming dismissal of the plaintiff's failure-to-warn claims on federal preemption grounds because the plaintiff failed to allege that the information in question "was unknown to the FDA prior to label approval" and, thus, the manufacturer could not have used the CBE process to alter the label).

The Court finds that Plaintiff has sufficiently pled that newly acquired information, i.e., information acquired after Jardiance was approved by the FDA on August 1, 2014, existed such that Defendant should have changed Jardiance's label through the CBE process. That is, Plaintiff has plausibly pled that there were adverse event reports and/or other information that warranted a label change after FDA approval based on the following allegations in the second amended complaint:

● "Since JARDIANCE's release, the FDA has received a significant number of reports of diabetic ketoacidosis among users of these drugs." (SAC ¶ 20, ECF No. 56.)

● "As part of its continued evaluation, on December 4, 2015[,] the FDA issued a new safety communication disclosing they had found 73 adverse events reported between March 2013 and May 2015 that required hospitalization due to ketoacidosis related to SGLT-2 inhibitors."[4] (*Id.* ¶ 38.)

● "There was no DKA warning at any time prior to FDA requiring the December 4, 2015[,] label change." (*Id.* ¶ 56.)

[4] Although Plaintiff may not rely on any of the adverse events that there were allegedly reported between March 2013 and August 1, 2014, she has plausibly alleged that some of the reports were made after August 1, 2014, until May 2015.

● "In 2015, multiple published case reports identified additional DKA events in patients treated with SGLT-2s." (*Id.* ¶ 58 (citations to reports omitted).)

Defendant argues that the second amended complaint does not explain how any post-approval reports were inconsistent with the reports that were already known to the FDA at the time of Jardiance's approval or how these reports could have supported a label change. Defendant cites "Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics and Medical Devices," 73 Fed. Reg. 2848 (Jan. 16, 2008), in support of its argument ("[I]f the reports of adverse events are consistent in type, severity, and frequency with information previously provided to FDA, such reports may not constitute newly acquired information appropriate for a CBE supplement."). This is an argument that is more appropriately made in a motion for summary judgment after discovery.

At this juncture, the Court finds that Plaintiff has sufficiently identified in the second amended complaint "newly acquired information" that could have plausibly supported a CBE change after FDA approval, and, thus, Plaintiff's post-approval failure-to-warn claims are not preempted. *See In re Celexa*, 779 F.3d at 41. ("*Wyeth* effectively reserves the launch of new drugs to the expertise of the FDA, but then preserves a wide scope for the states in requiring manufacturers to respond to information not considered by the FDA.") That is, Plaintiff has sufficiently alleged that Jardiance was unreasonably dangerous because there was no warning regarding the increased risk of DKA at any point prior to Plaintiff's injury and after Defendant was made aware of newly acquired information and that Defendant's knowledge of the propensity of Jardiance to cause DKA defeats the rebuttable presumption found in Tenn. Code Ann. § 29-28-104[5] that Jardiance was not defective or unreasonably dangerous.

[5] Tenn. Code Ann. § 29-28-104(a) provides as follows:

However, based on the learned intermediary doctrine, Plaintiff may bring claims only to the extent that she has alleged that her doctor would have made different prescribing decisions based on the post-approval reports of adverse events. The Tennessee Supreme Court has explained that doctrine as follows.

> Traditionally, the learned intermediary doctrine has been applied to warnings related to prescription drugs. *See* Victor E. Schwartz & Christopher E. Appel, *Effective Communication of Warnings in the Workplace: Avoiding Injuries in Working with Industrial Materials*, 73 Mo. L.Rev. 1, 22 (2008). The doctrine constitutes a defense by pharmaceutical manufacturers in cases where a plaintiff has suffered injury from a medication prescribed by a doctor. Physicians, who play a pivotal role in the distribution of prescription drugs, are the intermediaries relied on by manufacturers to give warnings to patients. A majority of jurisdictions, including Tennessee, recognize that a pharmaceutical manufacturer can discharge its duty to warn by providing the physician with adequate warnings of the drug's risks. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994). In Tennessee, the learned intermediary doctrine is applicable in failure to warn suits [when] a physician is the intermediary between a defendant pharmaceutical or other medical product manufacturer and an injured patient. *See id.*; *King v. Danek Med., Inc.*, 37 S.W.3d 429, 452–53 (Tenn. Ct. App. 2000); *Harden v. Danek Med., Inc.*, 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998).

Nye v. Bayer Cropscience, Inc., 347 S.W.3d 686, 701 (Tenn. 2011). Accordingly, the learned intermediary doctrine bars Plaintiff's claims premised on a failure to warn Plaintiff directly about an alleged risk of DKA. However, she can proceed on a claim that Defendant failed to warn her physician if the Court finds that she has plausibly alleged such a claim.

Concerning Defendant's failure to warn Plaintiff's physician, the second amended complaint alleges, *inter alia*, as follows.

> Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.

● "At all times relevant to this action, Defendant was engaged in disseminating inaccurate, false, and misleading information about JARDIANCE to consumers, including Plaintiff, and to health care professionals in the State of Tennessee, with a reasonable expectation that such information would be used and relied upon by consumers and health care professionals throughout the State of Tennessee." (SAC ¶ 11, ECF No. 56.)

● "Despite Defendant's knowledge of the increased risk of severe injury among users of JARDIANCE, they did not warn patients but instead continued to defend JARDIANCE, mislead physicians and the public, and minimize unfavorable findings." (*Id.* ¶ 22.)

● "Defendant knew of the significant risk of diabetic ketoacidosis caused by ingestion of JARDIANCE. However, Defendant did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community of the severity of such risks." (*Id.* ¶ 24.)

● "To the contrary, Defendant conducted nationwide sales and marketing campaigns to promote JARDIANCE, and they willfully deceived Plaintiff, Plaintiff's health care professionals, the medical community, and the general public as to the health risks and consequences of the use of JARDIANCE." (*Id.* ¶ 25.)

● "Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with taking JARDIANCE." (*Id.* ¶ 63.)

● "As a result of Defendant's actions, Plaintiff and Plaintiff's prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations, both separately and collectively." (*Id.* ¶ 64.)

● "Defendant expected JARDIANCE to reach, and they did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendant." (*Id.* ¶ 73.)

● "JARDIANCE, as manufactured and/or supplied by Defendant, was defective due to inadequate warnings or instructions, in that the label contained no warning regarding DKA whatsoever. Defendant knew or should have known that the product created significant risks of serious bodily harm to consumers as alleged herein, including but not limited to the risk of diabetic ketoacidosis, and they failed to adequately warn consumers and/or their health care professionals of such risks." (*Id.* ¶ 74.)

● "Defendant was aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendant knew or should have known that JARDIANCE caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of JARDIANCE, as referenced above, were known to Defendant, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients." (*Id.* ¶ 82.)

● "Defendant knew or should have known that the limited warnings disseminated with JARDIANCE was inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drugs. In particular, Defendant failed to communicate warnings and instructions to doctors that were appropriate and

adequate to render its products safe for ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the products for treatment of diabetes." (*Id.* ¶ 84.)

● "Defendant communicated information to health care professionals that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drugs safely for use by patients for the purposes for which they are intended." (*Id.* ¶ 85 (list of specific alleged deficiencies omitted).)

"In order to recover for failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product not otherwise known to the physician; and (2) that the failure to warn the physician was both a cause in fact and proximate cause of the plaintiff's injury." *King v. Danek Med., Inc.*, 37 S.W.3d 429, 452 (Tenn. Ct. App. 2000). Here, Plaintiff has adequately pled that the warnings were inadequate to apprise her physician of the risks of DKA associated with Jardiance, that this risk was otherwise not known to her physician, and that a post-approval warning pointing out the risks of DKA could have altered her physician's decision to prescribe Jardiance to her. However, Plaintiff has failed to state a claim to the extent that her theory is that Defendant failed to warn her physician of "other related health complications" (SAC ¶ 90, 114, ECF No. 56) because she has not specified any other alleged complications and inadequate warnings and, thus, has not plausibly provided the grounds of her entitlement to relief in this regard.[6]

Finally, Defendant has moved to dismiss Plaintiff's negligence claim as being insufficiently pled. The parties agree that all of Plaintiff's claims are covered by the TPLA, and

[6] In her response, Plaintiff has not disputed Defendant's contention that she cannot recover for an alleged failure to warn of non-specified "other related health complications." (Resp. pp. 14 – 20, ECF No. 64.)

Plaintiff has specifically pled her negligence claim under Tenn. Code Ann. § 29-28-102(6),[7] which is part of the TPLA. *See Higgs v. Gen. Motors Corp.*, 655 F. Supp. 22, 23 (E.D. Tenn. 1985) ("Indeed, it makes no difference whether the complaint is couched in terms of negligence, strict liability or breach of warranty, it has generally been held in the State of Tennessee that in order for a plaintiff to recover under any theory of product liability, the plaintiff must establish that the product was defective and unreasonably dangerous at the time the product left the control of the manufacturer.") "Thus, regardless of plaintiff's theories of recovery - which include strict liability, negligence, failure to warn, and breach of express and implied warranties - plaintiff must allege facts for the Court to infer that the [product was] 'defective' or 'unreasonably dangerous' at the time [it] left the control of the manufacturer." *Moore v. C.R. Bard, Inc.*, 217 F. Supp. 3d 990, 994 (E.D. Tenn. 2016). The Court finds that the second amended complaint sufficiently alleges that Defendant was negligent in not seeking to amend Jardiance's label post FDA approval to warn Plaintiff's physician of the possible side effect of DKA and that, if the physician had been warned, he would not have prescribed Jardiance for Plaintiff and she would not have developed DKA.

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> "Product liability action" for purposes of this chapter includes all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product. "Product liability action" includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever

Tenn. Code Ann. § 29-28-102(6).

In summary, Plaintiff has alleged sufficient facts under both a strict liability and negligence theory of recovery which, if proved at trial, would allow a jury to find that, under the TPLA, post FDA approval, Jardiance was in a defective condition or unreasonably dangerous at the time it left the control of Defendant because Jardiance's label did not warn Plaintiff's physician that DKA was a possible side effect of Jardiance and Plaintiff's physician would not have prescribed Jardiance if he had known of this possible side effect and Plaintiff's injury, i.e., developing DKA, was proximately caused by the defective product.[8] Accordingly, Defendant's motion to dismiss the portion of Plaintiff's complaint that alleges this narrow failure-to-warn claim is **DENIED**. The motion to dismiss the remaining portions of Plaintiff's complaint, including the failure-to-warn claim based on Jardiance's label at the time it was approved by the FDA, any claim that Plaintiff herself should have been warned about the possibility of developing DKA as a result of taking Jardiance, and Plaintiff's claim that she developed unspecified health related problems other than DKA, is **GRANTED**.

IT IS SO ORDERED.

s/ S. Thomas Anderson
S. THOMAS ANDERSON
CHIEF UNITED STATES DISTRICT JUDGE

Date: November 21, 2017.

[8] In support of its motion to dismiss, Defendant has cited *Fleming v. Janssen Pharm., Inc.*, 186 F. Supp. 3d 826 (W.D. Tenn. 2016), in which a court in this district granted the defendant's motion to dismiss. The ruling in *Fleming* is inapposite to this case because the allegations made by Plaintiff, as described above, are more specific and factually oriented than those made in *Fleming*. In that case, the plaintiff had "made only conclusory statements as to the failure of Defendants to warn about the dangers of Invokana" such as the allegation that "INVOKANA contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with INVOKANA, including the development of Plaintiff's injuries." *Id.* at 836.