

IN THE UNITED STATES COURT FOR THE DISTRICT OF UTAH
NORTHERN DIVISION

MELVIN STANLEY, individually and as
Personal Representative of the Estate of
PETER STANLEY,

Plaintiffs,

vs.

MYLAN INC., MYLAN TECHNOLOGIES,
INC. and MYLAN PHARMACEUTICALS

Defendants.

MEMORANDUM DECISION AND
ORDER DENYING IN PART AND
GRANTING IN PART
DEFENDANTS' MOTION TO
DISMISS

Case No. 1:09-CV-124 TS

This matter is before the Court on Defendants' Motion to Dismiss.¹ The motion has three parts: Defendants move to dismiss (1) the Complaint as a whole for failure to state a claim on which relief can be granted; (2) Paragraph 11 of the Complaint because Utah law bars strict liability for design defects in prescription drugs; and (3) Paragraph 25 because Utah statutes bar punitive damages for FDA-approved drugs.² Defendants acknowledge the statutory exception for

¹Docket No. 7.

²Docket No. 8.

cases where a plaintiff can show that the defendant knowingly misled the FDA, but they argue that this exception is impliedly preempted by federal law under *Buckman*.³

Plaintiffs oppose the motion on four grounds: (1) Defendants' Motion to Dismiss is untimely because their Answer was filed first; (2) the Complaint pleads sufficient factual allegations to provide Defendants with notice of the claims against them; (3) Plaintiff makes no strict-liability design-defect claim; and (4) under *Wyeth v. Levine*,⁴ federal law does not preempt the Utah law allowing punitive damages against defendants who knowingly mislead the FDA.⁵ Plaintiffs request that if the Court dismisses any of the claims for failure to plead sufficient facts, Plaintiffs be granted leave to amend the Complaint.

For the reasons below, the Court will deny the Motion to Dismiss with regard to all but the claims for failure to warn, breach of express warranty, and breach of implied warranty of fitness, and that the Court will grant Plaintiffs leave to amend those claims.

I. FACTUAL BACKGROUND

Plaintiffs allege that Peter Stanley ("Decedent") died on October 3, 2007, as a result of an overdose of fentanyl, which is a Schedule II controlled substance used as a pain reliever. Decedent was using, by prescription, 50 mcg fentanyl patches manufactured by Defendants. He acquired the patches from a local pharmacy. At the time of his death, Decedent had a fentanyl level of 19 ng/mL, which is in the lethal range.

³ *Id.* at 10-13 (referring to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (holding that state-law fraud-on-the-FDA claims are impliedly preempted by federal law)).

⁴ 129 S.Ct. 1187 (2009).

⁵ Docket No. 13

On September 23, 2009, Plaintiffs filed this wrongful-death action against Defendants. Plaintiffs allege strict liability because of manufacturing defect and failure to warn; negligence; negligent misrepresentation; breach of express and implied warranties; and gross negligence and intentional misconduct. Defendants simultaneously filed their Answer and a Motion to Dismiss on December 1, 2009.

II. DISCUSSION

A. TIMELINESS OF THE MOTION TO DISMISS

As a threshold matter, in Plaintiffs' opposition to this motion Plaintiffs claim that Defendants' Motion to Dismiss is untimely under Fed R. Civ. P. 12(b) because it was filed after the Defendants' Answer.⁶ Defendants admit that the Motion appears after the Answer on the case docket, but the two documents were filed on the same day within minutes of each other.⁷ Moreover, Defendants note that the Answer references the Motion to Dismiss, showing that the Defendants intended the Answer to incorporate the Motion.⁸ The Court finds Defendants' failure to electronically file their Motion before their Answer to be a mere oversight by Defendants' counsel and distinguishable from the authority cited by Plaintiffs.⁹ Therefore, the Court will consider Defendants' Motion to Dismiss.

⁶ See Fed. R. Civ. P. 12(b) ("A motion asserting [failure to state a claim upon which relief can be granted] must be made before pleading if a responsive pleading is allowed.").

⁷ Docket No. 14, at 3.

⁸ *Id.*

⁹ For example, Plaintiffs call the Court's attention to *Lewis v. Schafer*, 571 F. Supp. 2d. 54 (D.D.C. 2008), where the Court refused to consider Defendant's 12(b)(6) motion because Defendant had filed a responsive pleading 30 days prior. Certainly, a matter of minutes, as in the present case, is distinguishable from a lapse of a month.

B. LEGAL STANDRD FOR RULE 12(b)(6) MOTION

In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true well-pled factual allegations, viewing them in the light most favorable to the non-moving party.¹⁰ The Court “consider[s] the complaint as a whole”¹¹ and generally does not rely on any information outside the complaint.¹² Conclusions—statements in the complaint that “do not allege the factual basis for the claim”¹³—are not entitled to an assumption of truth.¹⁴

Rule 8 requires a pleader to provide “a short and plain statement of the claim showing that the pleader is entitled to relief.”¹⁵ The primary purpose of a pleading is to give the opposing party notice of the claim.¹⁶ In order to meet that objective, a claim must meet a standard of sufficiency outlined recently by the Supreme Court. Legal conclusions and “formulaic recitation of the elements of a cause of action” are not enough;¹⁷ factual allegations are necessary to give fair notice of the claim and the grounds on which it rests.¹⁸ This factual enhancement must be enough “to state a claim to relief that is plausible on its face.”¹⁹ “A claim has facial plausibility

¹⁰ *Ridge at Red Hawk, LLC v. Schneider*, 493 F.3d 1174, 1177 (10th Cir. 2007).

¹¹ *Lander v. Summit County School Dist.*, 109 Fed.Appx. 215, 217 (10th Cir. 2004).

¹² *Phillips v. Bell*, 365 Fed.Appx. 133, 142 (10th Cir. 2010).

¹³ *Rodeback v. Utah Fin.*, 2010 WL 2757243, at *1 (D. Utah July 13, 2010).

¹⁴ *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1950 (2009).

¹⁵ FED. R. CIV. P. 8(a)(2).

¹⁶ See 5 C. Wright & A. Miller, *Fed. Prac. & Proc. Civ.* § 1202 (3d ed. 2010); see also *Conley v. Gibson*, 355 U.S. 41, 47 (1957) (holding that a pleading should “give the defendant fair notice of what the plaintiff’s claim is and the grounds upon which it rests”).

¹⁷ *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

¹⁸ *Id.* at 556 n.3; see also *Iqbal*, 129 S.Ct. at 1950 (“While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.”).

¹⁹ *Twombly*, 550 U.S. at 570.

when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”²⁰

The Tenth Circuit has said that plausibility “refer[s] to the scope of the allegations in a complaint[;] if they are so general that they encompass a wide swath of conduct, much of it innocent, then the plaintiffs have not nudged their claims across the line from conceivable to plausible.”²¹ As the *Twombly* court said, there is a difference between allegations that are factually neutral and those that are factually suggestive.²² An allegation that does not lead to a reasonable inference of grounds for relief is not enough to cross the line from conceivable to plausible.

C. ADEQUACY OF THE PLEADINGS

Defendants argue that Plaintiff’s Complaint “fails to adequately plead a basis for relief pursuant to the requirements of [*Twombly*].”²³ Plaintiffs counter by stating that the Defendants failed to consider the Complaint as a whole, and in so doing, missed the factual underpinnings of the claims.²⁴ Plaintiffs plead seven causes of action: strict product liability, negligence, negligent misrepresentation, breach of express warranty, breach of implied warranty of fitness, breach of implied warranty of merchantability, and gross negligence/intentional misrepresentation. The Court will address the adequacy of the pleadings of these claims in turn.

²⁰ *Iqbal*, 129 S.Ct. at 1949.

²¹ *Phillips*, 365 Fed.Appx. at 139 (citing *Robbins v. Oklahoma*, 519 F.3d 1242 (10th Cir. 2008) and *Twombly*, 550 U.S. 544).

²² *Twombly*, 550 U.S. at 558 n

²³ Docket No. 8, at 2.

²⁴ Docket No. 13, at 7.

1. Strict product liability

Under the theory of strict product liability, Plaintiffs state two grounds for his First Cause of Action: manufacturing flaw and failure to warn. To prevail on his manufacturing-flaw claim under Utah law, Plaintiffs must prove that (1) the patch departed from its intended design,²⁵ (2) it was unreasonably dangerous to Decedent,²⁶ (3) it reached Decedent without substantial change in condition, and (4) it caused injury to Decedent.²⁷ Plaintiffs allege each of these elements, and Defendants are correct that those allegations, without any supporting factual averments, would constitute “a formulaic recitation of the elements”²⁸ of this cause of action. However, since the Court must look at the complaint as a whole, Plaintiffs’ statement of facts provides adequate support for the subsequent causes of action. Plaintiffs allege the patch was designed to administer non-lethal doses of fentanyl,²⁹ that Decedent was properly using the patch,³⁰ and that Decedent suffered a lethal dose of fentanyl.³¹ These factual allegations are enough to support the conclusions that the patch departed from its intended design, that it was unreasonably dangerous, and that it caused injury to Decedent. Therefore, with regard to the strict-liability manufacturing-flaw claim, the Court will deny the motion to dismiss.

²⁵ RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(a) (1998). The Utah Supreme Court has not yet adopted § 2 as Utah law, but the section reflects commonly followed principles that the Utah courts are likely to accept.

²⁶ RESTATEMENT (SECOND) OF TORTS § 402A (1965).

²⁷ *Id.*

²⁸ *Twombly*, 550 U.S. at 555.

²⁹ Docket No. 1, at ¶¶ 7-9.

³⁰ *Id.* at ¶¶ 6, 9

³¹ *Id.* at ¶ 10.

To prevail on his strict-liability failure-to-warn claim, Plaintiffs must prove that (1) Defendants did not give reasonable warnings to the prescribing physician about foreseeable risks of harm,³² and (2) the failure to warn was a legal cause of Decedent's death.³³ Plaintiffs have not alleged any underlying facts with regard to the lack of reasonable warnings, and a mere conclusory allegation of each element is not enough to nudge the claim from conceivable to plausible. Plaintiffs allege that Decedent was unaware of the patch's defective condition,³⁴ but offers no facts suggesting that the lack of awareness was due to Defendants' failure to warn the prescribing physician. While Decedent's alleged lack of awareness may help support the conclusion that his death was caused by the alleged failure to warn, it does not offer the necessary support for the conclusion that Defendants failed to warn of unavoidable risks.

Plaintiffs also allege that the best available scientific knowledge made the risks knowable.³⁵ Although this supports the conclusion that the risks were foreseeable to Defendants, it does not show any lack of reasonable warning by Defendants. Therefore, the complaint "has alleged—but it has not shown—that the pleader is entitled to relief."³⁶ Consequently, the Court will dismiss the strict-liability failure-to-warn claim without prejudice.

³² RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(d).

³³ *Id.* at § 6(a).

³⁴ Docket No. 1, at ¶ 11.

³⁵ *Id.* at ¶ 13.

³⁶ *Iqbal*, 127 S.Ct. at 1950.

2. *Negligence*

To recover on his Second Cause of Action for negligence, Plaintiffs must show that there was (1) a duty (2) which was breached, (3) causing harm.³⁷ Plaintiffs have pled facts about the nature of the relationship between Defendants (manufacturer of fentanyl patch) and Decedent (end consumer) that are enough to infer a duty on Defendants' part to not produce an unreasonably dangerous product.³⁸ Plaintiffs have likewise pled facts that lead to an inference that the duty was breached: Defendants manufactured the patch, it was not modified after leaving Defendants' control, Decedent was using the patch appropriately, and Decedent had a higher level of fentanyl in his blood than the patch should have delivered. Also, Plaintiffs have pled facts about the harm caused by the breach of duty: Decedent's untimely death, caused by the high level of fentanyl in his system. These factual averments are sufficient to give Defendants fair notice of the nature of the negligence claim. Therefore, the Court will deny the motion as to this cause of action.

3. *Negligent misrepresentation*

A claim for negligent misrepresentation must show that (1) false information was negligently given, (2) there was reasonable reliance on that information, and (3) reliance on the information caused harm.³⁹ "Such negligence may consist of failure to exercise reasonable care (a) in ascertaining the accuracy of the information, or (b) in the manner in which it was

³⁷ *Webb v. University of Utah*, 125 P.3d 906, 909 (Utah 2005).

³⁸ See *Delbridge v. Maricopa County Cmty. Coll. Dist.*, 893 P.2d 55, 58 (Ariz. 1994) ("Duty arises out of the relationship between the parties and imposes a legal obligation on one party for the benefit of the other party.").

³⁹ REST. 2D TORTS § 311(1).

communicated.”⁴⁰ In Utah, there does not need to be an affirmative representation of information to establish the claim. “[A]n omission may be actionable as a negligent misrepresentation where the defendant has a duty to disclose.”⁴¹ Therefore, Plaintiffs must show that there was such a duty to disclose, that Defendants failed to disclose, that Decedent reasonably relied on the information, and that Decedent was thereby harmed.

Plaintiffs allege that Defendants should have known that the patch created a risk of death by overdose under normal use and that Defendants failed to disclose this risk.⁴² As with the negligence claim, the duty comes from Defendants’ relationship as manufacturer of the patch to the Decedent as end consumer. The nature of the relationship is one of information asymmetry and reliance. Plaintiffs pled that Decedent wore the patch in reliance on Defendants’ representations and that such reliance caused the injury. The well-pled facts that Decedent was wearing the patch properly and that he died of a fentanyl overdose are enough to make the legal conclusions plausible under the *Twombly* standard. With respect to the negligent misrepresentation claim, the Court finds Plaintiffs’ pleadings are sufficient to withstand a motion to dismiss. Therefore, the Court will deny the motion as to this cause of action.

4. Breach of express warranty

To prove that there was an express warranty, Plaintiffs must show that (1) Defendants made affirmations or promises, including product descriptions, that (2) became a basis of the

⁴⁰ *Id.* at subsection (2).

⁴¹ *Smith v. Frandsen*, 94 P.3d 919, 923 (Utah 2004).

⁴² Docket No. 1, at ¶ 18.

bargain.⁴³ To recover for a breach of the warranty, he must show that (3) Decedent relied on the warranty⁴⁴ and (4) there were consequential damages, including personal injury.⁴⁵ Plaintiffs allege that Defendants made affirmations about the safety and effectiveness of the patch, including that it would safely deliver fentanyl over a period of time.⁴⁶ Statements that a product is safe or that it will perform in a certain way are express warranties.⁴⁷ Plaintiffs' averment that Defendants made promises about the safety and effectiveness of the patch would thus support the conclusion that there was an express warranty. However, Plaintiffs make no factual allegations as to how those promises were communicated or how they became a basis of the bargain. The allegations that Defendants communicated those affirmations and that they became a basis of the bargain are conclusions of law, mere recitations of the claim's elements. Because of the lack of supporting factual averments, Plaintiffs' claim for breach of express warranty is dismissed without prejudice.

5. Breach of implied warranty of fitness

For breach of implied warranty of fitness, Plaintiffs must show that (1) Defendants had reason to know (2) a particular purpose for which a good was required, (3) Decedent relied on Defendants' judgment to select an appropriate good for that purpose, and (4) the patch provided

⁴³ UTAH CODE ANN. § 70A-2-313 (express warranties).

⁴⁴ See *Mgmt. Comm. of Graystone Pines Homeowners Ass'n on Behalf of Owners of Condos. v. Graystone Pines, Inc.*, 652 P.2d 896, 900 (Utah 1982).

⁴⁵ UTAH CODE ANN. § 70A-2-715(2) (buyer's consequential damages).

⁴⁶ Docket No. 1, at 9.

⁴⁷ 63 AM. JUR. 2D PRODUCTS LIABILITY §§ 641-642.

by Defendants was unfit for that purpose.⁴⁸ “A ‘particular purpose’ differs from the ordinary purpose for which the goods are used.”⁴⁹ Plaintiffs have pled facts supporting a conclusion that the patch was designed and used for its ordinary purpose, but has not offered any factual basis for a conclusion that the patch had some purpose particular to the Decedent; nor have they offered any factual allegation supporting the conclusion that Defendants knew about any particular purpose. Therefore, the Court finds the pleadings fail to satisfy the requirements of 12(b)(6) as to the breach of implied warranty of fitness claim and will dismiss this claim without prejudice.

6. *Breach of implied warranty of merchantability*

To establish that there was a breach of implied warranty of merchantability, Plaintiffs must show that (1) Defendants sold a good, (2) which Decedent bought and (3) which did not meet one of the standards of merchantability—passes without objection; is of fair average quality; is fit for ordinary purposes; is of even kind, quality and quantity; is adequately contained, packaged and labeled; and conforms to promises on the packaging.⁵⁰ The Court finds that these elements are adequately pled and will deny the Defendants' Motion to Dismiss as to this claim.

⁴⁸ UTAH CODE ANN. § 70A-2-315 (implied warranty of fitness).

⁴⁹ UNIFORM COMMERCIAL CODE § 2-315 cmt. 2 (1965) (official U.C.C. comment that follows the Utah statute incorporating the Code). At least one state has decided that a buyer’s “particular purpose” can be the same as the product’s general purpose. See *Tennessee Carolina Transp., Inc. v. Strick Corp.*, 196 S.E.2d 711, 717-718 (N.C. 1973) (holding that in Pennsylvania an implied warranty of fitness protects the buyer whose purpose is the ordinary one for that product). However, the Utah courts have not followed suit, and the majority view seems to follow Comment 2 of the U.C.C. See, e.g., *Weir v. Federal Ins. Co.*, 811 F.2d 1387, 1393 (10th Cir. 1987) (holding that in Colorado, “[a] reason for purchasing a particular product beyond the ordinary reason for selecting that product must be shown in order to give rise to an implied warranty of fitness for a particular purpose”).

⁵⁰ UTAH CODE ANN. § 70A-2-314 (implied warranty of merchantability).

7. *Gross negligence and intentional misconduct*

Under Utah law, gross negligence is “the failure to observe even slight care; it is carelessness or recklessness to a degree that shows utter indifference to the consequences that may result.”⁵¹ To prevail on his Seventh Cause of Action, Plaintiffs must show that (1) Defendants knew of the risk their behavior would create and (2) nevertheless pursued that course of conduct with indifference to the consequences.⁵² Intentional misconduct is similar in nature but requires Plaintiffs to show not only indifference to the consequences, but actual intent.⁵³

As pled by Plaintiffs, these claims read like the boilerplate recitation of legal conclusions that *Twombly* and *Iqbal* disallow. However, the nature of this claim goes to the state of mind and knowledge of Defendants—something which Plaintiffs can’t be expected to know and about which they are allowed to plead generally.⁵⁴ Once the Court accepts as true the well-pled fact that Decedent died as a result of his use of the patch, as well as the general averment that Defendants knew about the danger of death, then the inference that Defendants were grossly negligent is a reasonably plausible one, and thus acceptable under the *Twombly* and *Iqbal* standard. Therefore, as to the gross negligence and intentional misconduct claims, the Court will deny the Motion to Dismiss.

⁵¹ *Pearce v. Utah Athletic Found.*, 179 P.3d 760, 767 (Utah 2008).

⁵² RESTATEMENT (THIRD) OF TORTS: LIAB. PHYSICAL HARM § 2 (2005).

⁵³ Intent is established when an actor “desires to cause consequences of his act, or [] he believes that the consequences are substantially certain to result from it.” RESTATEMENT (SECOND) OF TORTS § 8A.

⁵⁴ Even under the heightened specificity requirements of FED. R. CIV. P. 9(b) for fraud claims, plaintiffs are not required to plead with any particularity their averments about the intent, knowledge or state of mind of defendants. *See Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246, 1252 (10th Cir. 1997).

D. BAR ON STRICT LIABILITY FOR DESIGN DEFECT

In *Grundberg v. Upjohn Co.*,⁵⁵ the Utah Supreme Court accepted as Utah law the principle articulated in Comment k of the Restatement (Second) of Torts § 402A: “there are some products that have dangers associated with their use even though they are used as intended.”⁵⁶ Prescription drugs, because of their unique nature and in light of the regulatory process of the FDA, belong to this class of unavoidably dangerous products.⁵⁷ “The seller of such products . . . is not to be held strictly liable for unfortunate consequences attending their use.”⁵⁸ “Thus, under Utah law, [C]omment k shields manufacturers and sellers of prescription drugs from strict liability based on allegations of a design defect,” though they may be liable for claims based on manufacturing flaws and failures to warn.⁵⁹

In Paragraph 11 of his Complaint, Plaintiffs allege that the patch was defective “at the time it was designed,” and that the Defendants failed to use “a safer alternative design.”⁶⁰ Plaintiffs do not explicitly state a design-defect claim—and Plaintiffs agree with Defendants that Utah law blocks such a claim—but Plaintiffs assert that they nevertheless plead elements of a

⁵⁵ 813 P.2d 89 (Utah 1991).

⁵⁶ *Id.* at 92.

⁵⁷ *Id.* at 95.

⁵⁸ RESTATEMENT (SECOND) OF TORTS § 402A cmt. k.

⁵⁹ *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922 (Utah 2003) (citing *Grundberg*, 813 P.2d at 94).

⁶⁰ Paragraph 13 of the Complaint also says “Plaintiff would show that the Stanley Patch was designed . . . in a defective condition.”

design-defect claim to support the asserted claims.⁶¹ Defendants move to dismiss the paragraph as a whole for failure to state a claim. Because dismissing the paragraph would prejudice Plaintiffs' other claims, and because Defendants are not prejudiced by the paragraph, the Court will allow the case to proceed on the understanding that Plaintiffs will not press for a strict-liability design-defect claim.⁶²

E. STATE LAW BLOCKING PUNITIVE DAMAGES

As Defendants note in their Motion to Dismiss, UTAH CODE ANN. § 78B-8-203 disallows any award of punitive damages for harms caused by FDA-approved drugs. The statute includes an exception to that rule where a plaintiff can prove that the drug maker committed fraud on the FDA.⁶³ Other states have incorporated fraud-on-the-FDA provisions in their state code. The U.S. Supreme Court held in *Buckman Co. v. Plaintiffs' Legal Comm.*,⁶⁴ that policing fraud in the federal agencies is the domain of federal law.⁶⁵ Therefore, "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law."⁶⁶

⁶¹ Docket No. 13, at 6. Plaintiffs says the allegations in Paragraph 11 support his negligence claims, but Defendants note that they are included in the strict-liability cause of action. Docket No. 14, at 5.

⁶² See *Int'l Pulp Equip. Co. v. St. Regis Kraft Co.*, 59 F.Supp. 289 (D. Del. 1945) (allowing a claim to remain in the pleading, even though it was immaterial).

⁶³ UTAH CODE ANN. § 78B-8-203(2). The subsection reads in full:
The limitation on liability for punitive damages does not apply if it is shown by clear and convincing evidence that the drug manufacturer knowingly withheld or misrepresented information required to be submitted to the [FDA] under its regulations, which information was material and relevant to the claimant's harm.

⁶⁴ 531 U.S. 341 (2001).

⁶⁵ *Id.* at 347.

⁶⁶ *Id.* at 348.

At the end of its opinion, the Supreme Court limited that preemption to fraud-on-the-agency claims; it left undecided the question of whether fraud on the FDA could be part of a traditional state tort claim, such as negligence or manufacturing defect. The circuit courts have split on that question. The Sixth Circuit held in *Garcia v. Wyeth-Ayerst Labs.*,⁶⁷ that a Michigan statute protecting drug makers from strict liability for FDA-approved drugs was preempted to the extent that it allowed an exception where the defendant committed fraud against the FDA.⁶⁸ The *Garcia* court said any difference between a fraud-on-the-FDA claim and a traditional tort claim that incorporates a fraud-on-the-FDA exception is immaterial.⁶⁹ “*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims.”⁷⁰ Two years later, the Second Circuit looked at the same Michigan law in *Desiano v. Warner-Lambert & Co.*⁷¹ The *Desiano* court declined to follow *Garcia*, holding that the “clear presumption against preemption of long-standing common law claims” applied in a case that depended “only incidentally on evidence of [] fraud.”⁷² The *Desiano* court said that preempting “traditional common-law claims where fraud is not even a required element . . . would result in preemption of a scope that would go far beyond anything that has been applied in the past” and beyond what Congress has manifestly intended.⁷³

⁶⁷ 385 F.3d 961 (6th Cir. 2004).

⁶⁸ *See id.* at 965.

⁶⁹ *Id.* at 966.

⁷⁰ *Id.*

⁷¹ 467 F.3d 85 (2d Cir. 2006).

⁷² *Id.* at 98.

⁷³ *Id.* at 96.

The Tenth Circuit has not yet addressed this question. Since the circuit split developed, the issue has come up twice in the District of Utah. In *Grange v. Mylan Labs.*,⁷⁴ the Court followed the *Garcia* court's interpretation of *Buckman*.

The chief problems that *Buckman* sought to counteract are present whenever a plaintiff, as a prerequisite to collecting damages, is required to put on evidence that there was what amounts to fraud on the FDA. When such evidence is considered, state courts are essentially second-guessing the FDA[,] and drug companies, nervous about state litigation, will have an incentive to flood the FDA with information.⁷⁵

Thus, the Court held that UTAH CODE ANN. § 78B-8-203(2) is preempted to the extent that a plaintiff brings evidence of fraud on the FDA.⁷⁶

A year later in *Lake-Allen v. Johnson & Johnson, L.P.*,⁷⁷ the Court ruled on the same issue. There, the Court declined to follow *Garcia* and *Grange*, choosing instead to follow the U.S. Supreme Court's recent decision in *Wyeth v. Levine*.⁷⁸ "In *Wyeth*, the Court explained the rigidity of presumption against preemption, noting that federal preemption requires a 'clear and manifest purpose of Congress.'"⁷⁹ Because the defendants in *Lake-Allen* offered no evidence that

⁷⁴ 2008 WL 4813311 (D. Utah Oct. 31, 2008). The facts in *Grange* are almost identical to this case. It is a wrongful-death suit against Mylan stemming from the decedent's use of Mylan's fentanyl patch.

⁷⁵ *Id.* at *7.

⁷⁶ *Id.* ("There is no preemption, however, in a situation where a plaintiff invokes UTAH CODE ANN. § 78B-8-203(2) to seek punitive damages in cases where the FDA itself has found that there was fraud in the application process.").

⁷⁷ 2009 WL 2252198 (D. Utah July 27, 2009).

⁷⁸ 129 S.Ct. 1187 (2009). Because the Court found that *Wyeth* governed the issue, the Court did not consider the circuit split that arose in *Garcia* and *Desiano*. The decision followed the outcome of *Desiano*, but the reasoning followed *Wyeth*.

⁷⁹ *Lake-Allen*, 2009 WL 2252198, at *3 (quoting *Wyeth*, 129 S.Ct. at 1195).

Congress intended to preempt the Utah statute, their motion to dismiss the punitive-damages claim was denied.⁸⁰

In the case presently before the Court, Defendants invoke the Utah statute in seeking a dismissal of the punitive-damages claim. Plaintiffs argue that Subsection 2 of the statute allows them to pursue punitive damages because they allege that “Defendants knowingly withheld or misrepresented information required to be submitted to the [FDA] under its regulations.”⁸¹ The Court finds this Court's reading in *Lake-Allen* persuasive given the intervening Supreme Court decision in *Wyeth* and will allow the claim to proceed to discovery. The Court notes that the effect of *Wyeth* is to strengthen the presumption against preemption that was weakened in *Garcia*. As was the case in *Lake-Allen*, Defendants now before the Court offer no evidence that Congress intended to preempt the Utah statute. Therefore, the presumption against preemption holds, and Plaintiffs should get the chance to prove the elements of their claim. Consequently, Defendants' Motion to Dismiss as to this claim is denied.

F. LEAVE TO AMEND

Plaintiffs ask the Court for leave to amend the Complaint in the event the Motion to Dismiss was granted in whole or in part. As FED. R. CIV. P. 15(a)(2) makes clear, the Court “should freely give leave when justice so requires.” Unless there is “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the

⁸⁰ *Id.* at *4.

⁸¹ Docket No. 1, at ¶ 25.

amendment, futility of amendment, etc.,”⁸² the Court should allow amendment. The Court finds no evidence of any such circumstance in this case and Plaintiffs assert his ability to plead additional facts in support of any deficient claims.⁸³ Therefore, the Court will grant Plaintiffs leave to amend the pleadings with regard to the claims dismissed in this cause of action.

III. CONCLUSION


It is therefore,

ORDERED that Defendants’ Motion to Dismiss (Docket No. 7) is GRANTED in part and DENIED in part. The claims identified in this opinion for dismissal are done so WITHOUT PREJUDICE. It is further

ORDERED that Plaintiffs’ request for leave to amend is GRANTED. Plaintiffs shall have thirty (30) days from the date of the order to file an amended complaint with the Court.

DATED September 17, 2010.

BY THE COURT:



TED STEWART
United States District Judge

⁸² *Foman v. Davis*, 371 U.S. 178, 182 (1962).

⁸³ See Docket No. 13, at 24.