IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

LYNN WOODCOCK, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:09-cv-00507

MYLAN, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the court is the defendants' Motion to Dismiss [Docket 15]. The Motion presents two sets of issues. First, the Motion raises a choice-of-law issue. The defendants contend that Alabama law governs all of the plaintiff's claims. The plaintiff disagrees and argues that West Virginia law applies to her marketing defect claim. Second, regardless of which state's substantive law applies, the Motion challenges the sufficiency of the Complaint. As explained below, Alabama law governs the substantive issues in this case, except for the manufacturing defect claim. Furthermore, the plaintiff has sufficiently pleaded her causes of action. The defendants' Motion is therefore **DENIED**.

I. Factual and Procedural History

On May 8, 2009, Lynn Woodcock filed the Complaint as administrator of Thomas Woodcock's estate [Docket 1]. On May 14, 2009, before the defendants filed their answer, the plaintiff filed the First Amended Complaint [Docket 4]. The plaintiff asserts claims against Mylan, Inc., Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc. (collectively, the "Mylan

defendants" or "Mylan"), for injuries resulting in Thomas Woodcock's death. The Mylan defendants are West Virginia corporations with principal places of business in West Virginia. They design, manufacture, market, and distribute transdermal patches that administer the drug fentanyl, a Schedule II pain reliever (the "patch"). A patient uses the patch by applying it to his skin. Fentanyl is then absorbed through the skin and into the bloodstream.

Thomas Woodcock, an Alabama resident, was prescribed 75 mcg patches by his doctor for pain relief. Woodcock filled his prescription on May 8, 2007, in Alabama. He died there on May 10, 2007. At the time of his death, a lethal level of fentanyl was in his blood, and a 75 mcg Mylan fenatnyl patch was on his body. Woodcock "never abused the Patch or used it inappropriately." (First Am. Compl. ¶ 10.)

The plaintiff seeks to hold Mylan responsible for Woodcock's death on behalf of his estate. The Complaint asserts claims under five causes of action: (1) strict product liability; (2) negligence; (3) negligent misrepresentation; (4) breach of implied warranty of fitness; and (5) breach of the implied warranty of merchantability. Within the strict-product-liability cause of action, the plaintiff asserts claims for manufacturing defect, marketing defect, and design defect. She seeks actual and punitive damages exceeding $75,000.

On July 13, 2009, Mylan filed a Motion to Dismiss the Complaint. The plaintiff filed an opposition brief on July 27, 2009, and Mylan filed a Reply on August 5, 2009. This court possesses jurisdiction pursuant to 28 U.S.C. § 1332.

II. Motion to Dismiss Standard

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of a complaint. *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008). A court

reviewing the sufficiency of a complaint must "take the facts in the light most favorable to the plaintiff," but it "need not accept legal conclusions drawn from the facts" or "accept as true unwarranted inferences, unreasonable conclusions, or arguments." *Id.* (quoting *E. Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'ship.*, 213 F.3d 175, 180 (4th Cir. 2000)). Upon reviewing those facts, the court must determine whether the claims "give the defendant fair notice of what the . . . claim is and the grounds on which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957).

The plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Girratano*, 521 F.3d at 302 (quoting *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1974 (2007)). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 127 S. Ct. at 1964-65 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986), for the proposition that "on a motion to dismiss, courts 'are not bound to accept as true a legal conclusion couched as a factual allegation'"). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)[.]" *Id.* at 1965.

III. Discussion

This case presents challenging choice-of-law issues. The plaintiff, an Alabama resident, has filed suit in the Southern District of West Virginia against a West Virginia corporation for tortious injuries occurring in Alabama. A federal court sitting in diversity will generally apply the substantive law of the state in which it sits. *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). Thus, when a choice-of-law issue arises, a district court must sit in the place of the state court and apply the forum state's choice-of-law rules. *Klaxon Co. v. Stentor Electric Mfg. Co.*, 313 U.S. 487, 496-97

(1941); *Pen Coal Corp. v. William H. McGee and Co., Inc.*, 903 F. Supp. 980, 983 (S.D. W. Va. 1995). Here, I will first determine whether, under West Virginia choice-of-law principles, West Virginia or Alabama substantive law applies in this action. After determining which state's law applies, I will then turn to the sufficiency of the plaintiff's claims.

A. Choice of Law

In a tort action, West Virginia applies the law of the place of injury ("*lex loci delicti*"). *Chemtall, Inc. v. Madden*, 607 S.E.2d 282 (W. Va. 2004). It will not, however, apply a foreign state's law that contravenes West Virginia public policy. *Paul v. Nat'l Life*, 352 S.E.2d 550, 556 (W. Va. 1986) ("[W]e have long recognized that comity does not require the application of the substantive law of a foreign state when that law contravenes the public policy of this State."). The Supreme Court of Appeals of West Virginia has explained, however, that it does not intend for its choice-of-law principles to be "an invitation for forum shopping." *Id.* at n.14.

Not every conflicting foreign law, however, offends West Virginia public policy. The mere fact that "the substantive law of another jurisdiction differs from or is less favorable than the law of the forum state does not, by itself, demonstrate that application of the foreign law under recognized conflict of laws principles is contrary to the public policy of the forum state." *Howe v. Howe*, 625 S.E.2d 716 (W. Va. 2005) (internal quotation marks omitted). Indeed, the Supreme Court of Appeals has emphasized that it "does not take a request to invoke our public policy to avoid application of otherwise valid foreign law lightly." *Id.* at 724-25.

Mylan maintains that Alabama law applies to all of the plaintiff's claims, because Mr. Woodcock was an Alabama resident, he used the Mylan fentanyl patch in Alabama, and he died in Alabama. The plaintiff generally agrees "that Alabama, rather than West Virginia, law applies to this

action." (Pl.'s Br. Opp. Mot. Dismiss 4.) "But," the plaintiff asserts, "Defendants fail to note that West Virginia will not apply the law of a forum state that contravenes West Virginia public policy." (*Id.*) In particular, the plaintiff asserts that West Virginia law governs her marketing defect claim, because Alabama law applies the learned-intermediary doctrine, which West Virginia has rejected on public-policy grounds.

By the marketing defect claim, the plaintiff contends that Mylan "had reason [to] anticipate dangers inherent or reasonably for[e]seeable in the use of the Patch, but failed to provide adequate warning and/or instructions." (Compl. ¶ 16.) Furthermore, the plaintiff contends that after Mylan "knew or should have known of the risk of using the Patch, the . . . Defendants failed to communicate to the FDA, Decedent, physicians, distributors, pharmacists, and/or the general public, that proper use of the Patch could cause serious injury or death." (*Id.* ¶ 22.)

Generally, a manufacturer is liable for damages if it failed to adequately warn consumers about its products' risks. Alabama, however, applies the "learned-intermediary doctrine." That doctrine excuses a drug manufacturer from liability for failing to warn a consumer of the potential risks of using a drug, if the consumer's prescribing physician was aware of those risks. *Stone v. Smith, Kline 7 French Labs.*, 447 So.2d 1301, 1303 (Ala. 1984). West Virginia, however, has specifically rejected the learned-intermediary doctrine and continues to hold manufacturers liable for failure to warn. *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 914 (W. Va. 2007).

To identify the substantive law that controls the marketing defect claim, I must first determine whether West Virginia rejected the learned-intermediary doctrine on public-policy grounds. If so, then I must determine whether applying Alabama law in this case would violate that public policy.

1. West Virginia Has Rejected the Learned-Intermediary Doctrine on Public-Policy Grounds

In *Karl*, after surveying states that had either adopted or rejected the learned-intermediary doctrine, the court determined that changes in pharmaceutical marketing has rendered the doctrine obsolete. The court observed that the rise of direct advertising of pharmaceuticals has placed drug manufacturers in a more direct relationship with consumers. *Id.* at 909-10. In the court's view, the rise of direct advertising "obviate[d] each of the premises upon which the doctrine rests": the reluctance to interfere with doctor-patient relationship, the "absence in the era of 'doctor knows best' of need for the patient's informed consent," the inability of drug manufacturers to communicate with patients, and the subject's complexity. Furthermore, the court explained, a number of judicially created exceptions has severely undermined and complicated the doctrine. *See id.* at 911-13 ("Given the plethora of exceptions to the learned intermediary doctrine, we ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized.").

Finally, and most importantly here, the court emphasized the public-policy interest of having manufacturers bear the costs of warning consumers about a product's risks. "[I]t is the prescription drug manufacturers who benefit financially from the sales of prescription drugs and possess the knowledge regarding potential harms, and the ultimate consumers who bear the significant health risks of using those drugs," the court recognized. *Id.* Therefore, "it is not unreasonable that prescription drug manufacturers should provide appropriate warnings to the ultimate users of their products." *Id.* (quoting Olzem A. Bordes, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability?*, 81 U. Det. Mercy L. Rev. 267, 286-87 (2004) ("Public policy dictates that the manufacturer should warn the ultimate user of the harmful effects of its pharmaceuticals since it involves a person's health.")).

The analysis in *Karl* reveals that West Virginia's rejection of the learned-intermediary doctrine is grounded in public policy. The choice-of-law inquiry in this case thus turns on whether applying Alabama law to the plaintiff's marketing defect claim would violate West Virginia public policy.

2. Applying Alabama Law to the Marketing Defect Claim Would Contravene West Virginia Public Policy

Mylan contends that Alabama law should apply here, because applying Alabama law to this claim would not contravene West Virginia public policy. (Mem. Supp. Mot. Dismiss 4-5.) To support its claim, Mylan focuses on the lack of a connection between West Virginia and the facts of this case. Mylan maintains that it "does not seek[] the benefit of law alien to the underlying claim to shield itself from liability; rather Plaintiff seeks application of law alien to her claim to avoid application of the law of the state in which she resides and where Mr. Woodcock was injured." (*Id.* at 5.) It asserts that West Virginia has stated a reluctance to apply the public-policy exception to *lex loci delicti* when doing so would invite forum shopping, and, it maintains, that is exactly what the plaintiff is attempting to do here. (*Id.* (quoting *Paul*, 352 S.E.2d at 556 n.14).)

Other than Mylan's incorporation in West Virginia, this case has nothing to do with West Virginia. Mr. Woodcock was an Alabama resident, he was prescribed the Mylan patch in Alabama, he had the prescription filled in Alabama, he applied the patch in Alabama, and he died in Alabama. It certainly appears that the plaintiff is attempting to take advantage of West Virginia's more favorable tort law. Thus, applying West Virginia law to this claim will almost certainly invite forum shopping by plaintiffs dissatisfied with their home state's products liability laws. Nevertheless, I am convinced that the Supreme Court of Appeals of West Virginia, if presented with this question, would conclude that applying the learned-intermediary doctrine would violate West Virginia public policy.

Despite its stated preference that the public-policy exception to *lex loci delicti* should not be a tool of forum shoppers, the court has taken a different approach in practice. Indeed, the Supreme Court of Appeals has recognized that West Virginia public policy is implicated in cases where an out-of-state plaintiff seeks to recover for an out-of-state injury.

In *Mills v. Quality Supplier Trucking, Inc.*, 510 S.E.2d 280 (W. Va. 1998), the plaintiff—the widow of truck driver who had been shot and killed by another truck driver in Maryland—sued the trucking company that employed the man who shot her husband for wrongful death and for negligent hiring. The trucking company was a citizen of Ohio and Delaware. The plaintiff and her late husband were, at the time of the shooting, West Virginia residents, but the plaintiff subsequently moved to another state after her husband's death. *Mills*, 510 S.E.2d at 281-82. The Supreme Court of Appeals addressed a certified question as to which state's substantive law applied, the law of the forum (West Virginia) or the law of the place of injury (Maryland). *Id.* at 281. The court held that Maryland law applied to the negligent-hiring claim. But, the court concluded, West Virginia law governed the wrongful-death claim, because Maryland allowed the defense of contributory negligence, a doctrine that West Virginia had rejected. *Id.*

In arguing that the public-policy exception did not apply, the defendant trucking company made an argument similar to Mylan's. It contended that "the public policy exception to the lex loci delicti doctrine should be used sparingly and [] is applicable only where the rights of West Virginia residents will be prejudiced by application of the foreign state doctrine, emphasizing that [the plaintiff] was a Georgia resident at the time of filing and now is a Tennessee resident." *Id.* at 283. The plaintiff, however, maintained "that the public policy exception is designed to enforce the public policy of West Virginia in actions filed [there] and is not dependent on the residence of the plaintiff."

Id. The court rejected the defendant's argument. It explained, "We decline to structure our determination of the appropriate application of the public policy exception upon the specific actions of the parties in any particular case. Were we to adopt [the defendant's] proposition, we would be relegated to determining the application of an integral rule of conflicts of law upon a case by case analysis." *Id.* The court thus applied the public-policy exception to *lex loci delicti* and held that West Virginia law governed the wrongful-death claim. *Id.*

In rejecting the learned-intermediary doctrine in *Karl*, the Supreme Court of Appeals recognized West Virginia's public policy of holding corporations responsible for the harms they create. Thus, applying the learned-intermediary doctrine in this case would contravene West Virginia's public policy of placing liability on the cheapest cost avoider—in this case, Mylan. *See generally* Guido Calabresi, *The Costs of Accidents: A Legal and Economic Analysis* (1970); *cf. Hamilton v. Accu-Tek*, 62 F. Supp. 2d 802, 827 (E.D.N.Y. 1999) ("The tort law can properly impose a strong incentive on manufacturers to reduce the risk of injury by marketing and distributing their products reasonably."). Although Mr. Woodcock was not a West Virginia resident, Mylan is. As a West Virginia corporation, Mylan has taken advantage of the laws of West Virginia, and it cannot now complain that it is being held to their consequences. Presumably, Mylan has developed its business around an expectation that, as a West Virginia corporation, it will be subject to West Virginia tort law.

Second, although Mylan cites cautionary language from the Supreme Court of Appeals expressing concern for forum shopping, that language addresses a circumstance not present by these facts. In *Paul*, the Supreme Court of Appeals stated in a footnote,

> [W]e do not intend [the public-policy exception] as an invitation to flagrant forum shopping. For example, were a resident of a guest statute jurisdiction to sue another

> resident of a guest statute jurisdiction over an accident occurring in a guest statute jurisdiction, the simple fact that the plaintiff was able to serve process on the defendant within our State borders would not compel us to resist application of any relevant guest statute. This State must have some connection with the controversy above and beyond mere service of process before the rule we announce today will be applied. In other words, venue must be proper under some provision other than W.Va. Code 56-1-1(a)(4).

Paul, 352 S.E.2d at 556 n.14. In contrast, West Virginia's interest in this case extends beyond service of process within the state. Mylan is a West Virginia corporation subject to general personal jurisdiction here. West Virginia thus has an interest in this litigation beyond the attenuated circumstance addressed in *Paul*.

Because West Virginia has rejected the learned-intermediary doctrine on public-policy grounds and applying Alabama law to the marketing defect claim would violate that public policy, West Virginia law applies to that claim. Having determined that Alabama law applies to all of the plaintiff's causes of action, save for the marketing defect claim, I will now address whether the plaintiff's pleadings are sufficient.

B. Motion to Dismiss

Mylan asserts that the Complaint should be dismissed because the plaintiff has failed to "satisfy the pleading requirements set forth by the United States Supreme Court." (Mem. Supp. Mot. Dismiss 5.) Mylan contends that the plaintiff has failed to adequately plead her claims, because she has merely provided conclusory recitations of the elements of each count that she pursues.

1. The Strict Liability Claims

a. The Manufacturing Defect Claim

In Alabama, strict-product-liability claims arise under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD"). The AEMLD is a judicially created product liability theory that is

based on section 402A of the Restatement (Second) of Torts. *Casrell v. Altec Indus., Inc.*, 335 So.2d 128 (Ala. 1976). To state a claim under the AEMLD, a plaintiff must allege (1) that "he suffered an injury or damage to himself . . . by one who sells a product in a defective condition unreasonably dangerous to the plaintiff as the ultimate user or consumer"; (2) that the "seller is engaged in the business of selling such a product"; and (3) the product "is expected to and does reach the consumer without substantial change in the condition in which it was sold." *Tanksley v. ProSoft Automation, Inc.*, 982 So.2d 1046, 1049-50 (Ala. 2007) (internal alterations and quotation marks omitted).

With regard to the manufacturing defect claim, Mylan maintains that, under Alabama law, "the existence of a defect cannot be inferred from a mere product failure or an accident involving the product." (Mem. Supp. Mot. Dismiss 8.) Instead, Mylan contends, the plaintiff "'must affirmatively show a defect in the product.'" (*Id.* at 9 (quoting *Verchot v. General Motors Corp.*, 812 So.2d 296 (Ala. 2001)).) Rather than satisfying her pleading burden, Mylan asserts, the plaintiff has simply given "a recital of the AEMLD's legal requirements adjusted to make out a putative claim," and that this claim must therefore be dismissed.

Contrary to Mylan's assertions, the plaintiff has sufficiently alleged that the patch suffered from a manufacturing defect that was the proximate cause of Mr. Woodcock's death. The plaintiff has alleged that a properly manufactured patch "will release a certain amount of fentanyl into a patient at a certain rate, and thus produce a certain level of fentanyl in the blood of the patient. In other words, if a Patch functions as intended and it is properly used by the patient, the patient should not receive a harmful does of fentanyl." (Pl.'s First Am. Compl. ¶ 10.) The patch used by Mr. Woodcock, the plaintiff asserts, was manufactured defectively because it "can and does cause lethal

levels of fentanyl in patients" and "decedent had a lethal fentanyl blood concentration at the time of his death" despite "never abus[ing] the Patch or us[ing] it inappropriately." (*Id.* ¶¶ 10-12.)

Mylan's assertion that the plaintiff must identify a specific manufacturing defect also fails. Under certain circumstances, Alabama law allows the inference of a non-specific defect. In *Rudd v. General Motors Corp.*, 127 F. Supp. 2d 1330 (M.D. Ala. 2001), the district court extensively reviewed Alabama law and concluded that a plaintiff may make out a prima facie claim of defect under the AEMLD without alleging a specific defect:

> From its earliest formulations, the AEMLD has been construed as allowing plaintiffs to show a product was defective or unreasonably dangerous despite a lack of direct evidence identifying a specific defect: a defect is that which renders a product unreasonably dangerous, i.e., not fit for its intended purpose. . . . It makes no difference whether [the product] is dangerous by design or defect. . . . More recent AEMLD cases . . . emphasize that a plaintiff must affirmatively come forward with some evidence that the product had a defect . . . . But, in no way do these cases reverse course on the tradition that a plaintiff need not have evidence specifically identifying the exact nature of the defect.

Rudd, 127 F. Supp. 2d at 1345-46 (internal citations and quotation marks omitted).[*] The plaintiff has thus sufficiently pleaded a cause of action for a manufacturing defect under the AEMLD, and the Motion to Dismiss this claim is **DENIED**.

b. The Marketing Defect Claim

---

[*] To be sure, Alabama courts have been reluctant to infer a defect based solely on an injury, accident or product failure when other factors could likely have caused the injury or product failure. *See, e.g.*, *Sears, Roebuck, & Co., Inc.*, 395 So.2d at 996 ("The mere fact of a tire blowout does not demonstrate the manufacturer's negligence, nor tend to establish that the tire was defective. Blowouts can be attributed to myriad causes, including not only the care with which the tires are maintained, but the conditions of the roads over which they are driven and the happenstance striking of damaging objects.") (internal citations omitted); *Verchot v. General Motors Corp.*, 812 So. 2d 296, 299 (Ala. 2001) (granting summary judgment where "plaintiffs'evidence indicating that the accident could have been attributable to an internal defect in the master cylinder is necessarily speculative and nonselective"). In this case, however, the plaintiff has sufficiently alleged that a defect in the patch, and nothing else, caused Mr. Woodcock's death.

Next, Mylan contends that the plaintiff's marketing defect claim is insufficiently pleaded. "[T]o establish a failure-to-warn claim," Mylan maintains, "Plaintiff must plead and prove not only the inadequacy of the warnings provided, but also that, had the warning been 'adequate' by the Plaintiff's reckoning, this would have averted Decedent's injury." (Mem. Supp. Mot. Dismiss 11.)

In West Virginia, "[a] failure to warn cause of action covers situations when a product may be safe as designed and manufactured, but which becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner." *Wilkinson v. Duff*, 575 S.E.2d 335, 340 (W. Va. 2002) (internal quotation marks omitted). To determine whether the defendant had a duty to warn, "the fundamental inquiry is whether it was reasonably foreseeable that the product would be unreasonably dangerous if distributed without a particular warning." *Id.*

The plaintiff asserts that "[a]fter the . . . Defendants knew or should have known of the risk of using the Patch, the . . . Defendants failed to communicate to the FDA, Decedent, physicians, distributors, pharmacists, and/or the general public, that proper use of the Patch could cause serious injury or death." (*Id.* ¶ 22.) Furthermore, the plaintiff alleges that "misrepresentations were made to the FDA, Decedent, physicians, pharmacists, as well as the general public" regarding the risks of using the Mylan patch, (*id.* ¶ 23), and that Mylan "fail[ed] to provide adequate training, knowledge or information to physicians, distributors, or sellers of the product." (*Id.* ¶ 20.) The plaintiff thus alleges that Mylan failed to warn Mr. Woodcock of the risks attendant to using the patch. If true, this satisfies the requirements of a failure-to-warn claim in West Virginia. The Motion to Dismiss the marketing defect claim must therefore be **DENIED**.

c. The Design Defect Claim

In the design defect claim, the plaintiff alleges that the Mylan patch was defectively designed and that this defect caused Mr. Woodcock's death. To support this claim, the plaintiff asserts that the Mylan patch "can and does cause lethal levels of fentanyl in patients," (First Am. Compl. ¶ 11), and that Mylan "could have used a safer alternative design [that] was economically and technologically feasible at the time of manufacture," (*id.* ¶ 17). Mylan contends that this claim is insufficiently pleaded, both because the mere existence of a safer alternative design does not establish liability, and because the plaintiff has "fail[ed] to provide any factual basis for her assertion that a[] feasible and safer alternative to the [patch] as designed existed at the relevant time." (Mem. Supp. Mot. Dismiss 10.)

To prevail on a design defect claim under Alabama law, a plaintiff must prove that a safer, practical, alternative design was available to the manufacturer at the time the product was manufactured. *Beech v. Outboard Marine Corp.*, 584 So.2d 447, 450 (Ala. 1991). The Supreme Court of Alabama has explained that

> [t]he existence of a safer, practical, alternative design must be proved by showing that: (a) [t]he plaintiff's injuries would have been eliminated or in some way reduced by use of the alternative design; and that (b) taking into consideration such factors as the intended use of the [product], its styling, cost, and desirability, its safety aspects, the foreseeability of the particular accident, the likelihood of injury, and the probable seriousness of the injury if that accident occurred, the obviousness of the defect, and the manufacturer's ability to eliminate the defect, the utility of the alternative design outweighed the utility of the design actually used.

Beech, 584 So.2d at 450. Therefore, in this case, the plaintiff must allege that an alternative design existed that would not have delivered a lethal dose of fentanyl to Mr. Woodcock, and that the alternative design would have been safer than the design that Mylan actually used.

The plaintiff has satisfied her pleading burden. She asserts that "the defective design of the Patch rendered it unsafe for its intended or reasonably foreseeable use because it failed comply with

existing technology or the state of the art. The Mylan Defendants could have used a safer alternative design that was economically and technologically feasible at the time of the manufacture. The design defect was a proximate cause of Decedent's death and the damages claimed herein." (First Am. Compl. ¶ 17.) To require more under Rule 8 would be to impose a heightened pleading standard that would require the plaintiff to produce evidence before discovery has commenced. The court thus **DENIES** the Motion to Dismiss the design defect claim.

B. The Negligence and Negligent-Misrepresentation Claims

Mylan also challenges the sufficiency of the plaintiff's claims for negligence and negligent misrepresentation. It asserts that the plaintiff's factual allegations with regard to these claims are merely legal conclusions, and that the claims must therefore be dismissed. The court disagrees.

1. Negligence

Alabama common law, not the AEMLD, governs the plaintiff's negligence and negligent-misrepresentation claims. *Tillman v. R.J. Reynolds Tobacco Co.*, 871 So.2d 28 (Ala. 2003). To state a claim for negligence, the plaintiff must allege that Mylan had a duty, that it breached that duty, and that the breach caused the plaintiff's injury. *See Albert v. Hsu*, 602 So.2d 895, 897 (Ala. 1992). Here, the plaintiff has pleaded those elements, (Compl. ¶ 19), and that claim is supported by twenty-two separate factual allegations that adequately support the negligence claim, (*id.* ¶ 20). This is sufficient under Rule 8. The Motion to Dismiss the negligence claim is thus **DENIED**.

2. Negligent Misrepresentation

Likewise, the plaintiff has sufficiently pleaded a cause of action for negligent misrepresentation. A negligent-misrepresentation claim requires the plaintiff to allege "that the defendant made a false representation of a material fact and that the plaintiff relied upon the false

representation to his detriment." *Nat'l Sec. Ins. Co. v. Donaldson*, 664 So.2d 871, 876 (Ala. 1995). "[A] defendant's recklessness in making a false representation is sufficient to support a fraud claim; the actual intention to defraud is often not needed." *Id.*

Here, the plaintiff alleges that Mylan

> represented and marketed the Patch as being safe and effective. After the Mylan Defendants knew or should have known of the risk of using the Patch, the Mylan Defendants failed to communicate to the FDA, Decedent, physicians, distributors, pharmacists, and/or the general public, that proper use of the Patch could cause serious injury and/or death. The Mylan Defendants instead communicated to all such persons/entities that the Patch was safe for use. Specifically, the Mylan Defendants' misrepresentations include, without limitation, a representation that the Patch would produce a maximum fentanyl blood concentration that was much lower that the fentanyl concentration found in Decedent's blood at the time of his death and a representation that the Patch was safe for use and a representation that the Patch can be used with other medications.

(Compl. ¶ 22.) The Complaint then sets forth seven paragraphs of facts to support this claim. (*Id.* ¶ 23.) These facts, if true, entitle the plaintiff to relief. As such, the Motion to Dismiss the negligent-misrepresentation claim must be **DENIED**.

C. The Implied-Warranty Claims

Mylan contends that the warranty claims "should be dismissed because Alabama law does not recognize their status as stand-alone claims in an action under the AEMLD." (Mem. Supp. Mot. Dismiss 14). This argument lacks merit. Alabama has recognized that a plaintiff may independently pursue AEMLD claims and implied-warranty claims. *Spain v. Brown & Williamson Tobacco Corp.*, 872 So.2d 101, 111 (Ala. 2003) ("[A] claim alleging breach of an implied warranty of merchantability is separate and distinct from an AEMLD claim and is viable to redress an injury caused by an unreasonably dangerous product."). Furthermore, Mylan contends that the plaintiff's implied-warranty claims must be dismissed because they are "duplicative of those made in

connection with the product liability claims, and are as insufficient in this context as they are in that one." (*Id.*) The court will address this contention below.

1. Implied Warranty of Fitness

Alabama law provides, "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Ala. Code § 7-2-315. The plaintiff must allege that (1) there existed an implied warranty, (2) that the warranty was breached, and (3) that damages resulted from the breach. *Barrington Corp. v. Patrick Lumber Co., Inc.*, 447 So.2d 785, 787 (Ala. Civ. App. 1984). The plaintiff asserts that

> [t]he Mylan Defendants had reason to know that the particular purpose for which their products were to be used. The Mylan Defendants had reason to know that the buyer was relying on the skill and judgement of the Mylan Defendants to select or furnish suitable products. The product supplied by the Mylan Defendants was unfit for the particular purposes for which it was purchased. This lack of fitness for the product's purpose was a proximate cause of the death of Decedent . . . .

(First Am. Compl.¶ 24.) This provides a sufficiently plausible factual basis to support going forward on the implied-warranty-of-fitness claim. The Motion to Dismiss this claim is therefore **DENIED**.

2. Implied Warranty of Merchantability

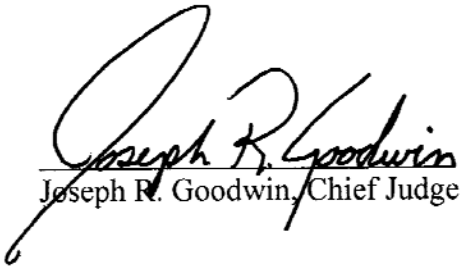
With regard to the plaintiff's claim for implied warranty of merchantability, Alabama law provides that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Ala. Code § 7-2-314. To state a claim under this cause of action, the plaintiff must allege that (1) the defendant was a merchant with respect to the fentanyl patch; (2) Mylan sold the patch to Mr. Woodcock; (3) Mr. Woodcock used the patch

for the ordinary purpose for which it is sold; (4) that the patch was defective; and (5) that the defects in the patch caused Mr. Woodcock's death. The plaintiff sufficiently alleges these elements. She asserts that the patch was "not of fair or average quality within the description," that it "was unfit for the ordinary purposes for which fentanyl patches are used," that "it was inadequately packaged and labeled," and that "it did not conform to the affirmations of fact made on the label." (First Am. Compl. ¶ 25.) The Motion to Dismiss this claim is therefore **DENIED**.

IV. Conclusion

As explained above, the plaintiff has sufficiently pleaded her claims. The court thus **DENIES** Mylan's Motion to Dismiss [Docket 15]. The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party. The court further **DIRECTS** the Clerk to post a copy of this published opinion on the court's website, www.wvsd.uscourts.gov.

ENTER: October 14, 2009



Joseph R. Goodwin, Chief Judge