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U.S. DISTRICT COURT
N.D. OF ALABAMA

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

ROBIN J. COMPSTON, as Personal Representative and Administrator of the Estate of John Jacob Compston, III,	)	
Plaintiff,	)	
v.	)	**Case No. 2:18-cv-1460-MHH**
MYLAN TECHNOLOGIES, INC., et al.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, defendants Mylan Pharmaceuticals, Inc. and Mylan Technologies, Inc. have asked the Court to dismiss the claims brought against them in this wrongful death action. (Doc. 17). According to Ms. Comspton's allegations in her amended complaint, the Mylan defendants design, manufacture, and market the Mylan Fentanyl Transdermal System, a patch that doctors prescribe to deliver therapeutic levels of fentanyl to treat chronic pain. (Doc. 16, p. 3). Ms. Compston alleges that her husband applied a prescribed fentanyl patch on September 14, 2016 and died one day later. (Doc. 16, p. 3). A senior state medical examiner reported that the cause of death was "Multiple

drug toxicity (Fentanyl, Alprazolam, and Zolpidem)." (Doc. 1-1, p. 8; *see also* Doc. 16, p. 3, ¶ 9).

To recover damages from Mylan for her husband's death, in her amended complaint, Ms. Compston alleges claims for negligent design, manufacturing, marketing, and distribution of the fentanyl patch and failure to provide adequate warning of the risks associated with use of the fentanyl patch. She also asserts a claim under the Alabama Extended Manufacturer's Liability Doctrine – or AEMLD, alleging that the fentanyl patch distributed to her husband was defective or unreasonably dangerous in its design, manufacture, sale, and product warnings. (Doc. 16, pp. 4–8). In response to Mylan's motion to dismiss, Ms. Compston concedes that her "claims for design defect and failure to warn are preempted by federal law." (Doc. 19, p. 2). Therefore, the Court must resolve Mylan's motion to dismiss with respect to Ms. Compston's manufacturing defect claim.

Ms. Compston alleges that the fentanyl patch that Mr. Compston used was defective in that it lacked "safe matrix technology or sealing integrity to assure timely and safe distribution" of the patch's "ingredients/medication," and that as a consequence, Mr. Compston had in his system at the time of his death "a fentanyl level of 14 ng/ml, which is greater than the published therapeutic level and is within the level reported to be toxic or fatal." (Doc. 16, p. 7, ¶¶ 9, 16, 22). Mylan persuasively argues that Ms. Compston's allegation concerning "safe matrix

technology" is a criticism of the patch's design and therefore fails along with Ms. Compston's other design defect theories. (Doc. 20, pp. 4–5). Mylan does not specifically address Ms. Compston's allegation that the sealing integrity of the patch that Mr. Compston used did not assure "timely and safe distribution" of fentanyl, causing Mr. Compston to receive a fatal amount of the drug.

To evaluate this manufacturing defect theory, the Court must view the allegations in the amended complaint in the light most favorable to Ms. Compston and draw inferences from the factual allegations in the light most favorable to her. *Sun Life Assurance Co. v. Imperial Premium Fin., LLC*, 904 F.3d 1197, 1207 (11th Cir. 2018). Under Alabama law, to assert an AEMLD claim for a manufacturing defect, a plaintiff must allege that she (or her decedent) suffered an injury "by one who sells a product in a defective condition unreasonably dangerous" to the plaintiff (or her decedent) "as the ultimate user or consumer" of the product, that the defendant is "engaged in the business of selling such a product," and that the product has reached the end-user "without a substantial change in the condition in which it was sold." *Casrell v. Altec Indus., Inc.*, 335 So. 2d 128, 132–33 (Ala.1976), quoted with approval in *Tanksley v. ProSoft Automation, Inc.*, 982 So. 2d 1046, 1049–50 (Ala. 2007). Contrary to Mylan's assertion, Alabama law does not require a plaintiff asserting a manufacturing defect claim to allege a specific flaw in the manufacturing process. (Doc. 17, p. 26). *See McDaniel v. Mylan, Inc.*, No. 7:19-cv-209 (N.D. Ala.

Dec. 16, 2019) (Doc. 21, p. 16) ("Because proof of the specific manufacturing error is not a required element of the claim, pleading facts pertinent to the specific manufacturing error is not necessary to state a plausible claim to relief."). Ms. Compston has sufficiently alleged that the fentanyl patch that Mr. Compston used had a defective seal, and that that manufacturing defect caused an unsafe level of fentanyl to be released into his system.[1]

Within 14 days of the entry of this order, the parties shall please confer and submit a Rule 26 report consistent with the initial order in this matter, (Doc. 22).

DONE and **ORDERED** this January 27, 2020.

MADELINE HUGHES HAIKALA
UNITED STATES DISTRICT JUDGE

[1] Ms. Compston has alleged that the fentanyl patch that her husband used reached her husband "without change in the condition in which it was produced, manufactured, sold, distributed, and marketed" by Mylan. (Doc. 16, p. 6, ¶ 19).