IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

TYLER GLEAVES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. N25C-12-106 SKR
	)	
HIGHRIDGE MEDICAL, LLC	)	
	)	
	)	
Defendant.	)	

Submitted: August 31, 2026
Decided: November 24, 2026

ORDER DENYING PLAINTIFF'S MOTION FOR REARGUMENT AND GRANTING PLAINTIFF'S REQUEST FOR LEAVE TO AMEND

Upon consideration of Plaintiff's Motion for Reargument of the Court's August 11, 2026 Oral Ruling which denied Defendant's Motion to Dismiss as to Count I and granted Defendant's Motion to Dismiss as to Counts II and III, or, in the alternative, for leave to amend the Complaint (the "Motion")[1] and Defendant's opposition thereto[2], the Court finds as follows:

1. Before addressing the merits of Plaintiff's arguments, the Court notes the governing standard. Superior Court Civil Rule 59(e) provides that a party may submit a motion for reargument "within 5 days after the filing of the Court's

[1] D.I. 34 [hereinafter "Mot."].

[2] D.I. 39 [hereinafter "Opp'n"].

opinion or decision."[3] A motion for reargument will be denied unless the Court overlooked controlling precedent or legal principles, or misapprehended the law or the facts in a manner affecting the outcome of the decision.[4] Conversely, where a motion for reargument represents a mere rehash of arguments already decided by the Court or presents new arguments not previously raised, the motion will be denied.[5]

2. On August 11, 2026, the Court issued an oral ruling denying dismissal of Count I (strict liability manufacturing defect), and granting dismissal of Counts II (strict liability failure to warn) and III (general negligence) (the "Ruling").[6]

3. In response to the Ruling, Plaintiff filed the instant Motion asserting two bases for reargument and, alternatively, requesting leave to amend the Complaint pursuant to Superior Court Civil Rule 15(a).

4. First, Plaintiff takes issue with the Court's application of *Bulox v. CooperSurgical, Inc.* to bar Count II, contending that the Court extended *Bulox* beyond its holding in an outcome-determinative misapprehension of law.[7] Specifically, Plaintiff emphasizes that *Bulox* is materially distinguishable because

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[3] Super. Ct. Civ. R. 59(e).

[4] *Bayer CropScience LP v. Corteva, Inc.*, 2025 WL 1504360, at *1 (Del. Super. May 5, 2025).

[5] *Id*. (citations omitted).

[6] *Tyler Gleaves v. Highridge Medical, LLC*, C.A. No. N25C-12-106 SKR, at 3:6–15:19 (Del. Super. Aug. 11, 2026) (TRANSCRIPT) (D.I. 42) [hereinafter "Ruling"].

[7] *See* 773 F. Supp. 3d 351 (S.D. Tex. 2025); *see* Mot. ¶¶ 5–6.

the plaintiff's theory there rested entirely on a failure to report adverse events to the FDA coupled with a failure to identify any independent Texas duty upon which to ground liability.[8] Here, by contrast, Plaintiff argues that the allegations are broader, encompassing assertions that Defendant made false FDA-required communications to physicians and consumers. According to Plaintiff, this conduct gives rise to state-law liability based on Texas' traditional duty to provide truthful risk information to physicians and consumers.[9] Ultimately, Plaintiff maintains that because federal and state law both prohibit disseminating inaccurate information regarding medical devices—the former to the FDA and the latter to doctors and consumers—and, because state law imposes this duty independently of FDCA disclosure requirements, Count II qualifies as a non-preempted parallel claim.[10]

5. The Court disagrees, as it already addressed and rejected these arguments in the Ruling. *Bulox* makes clear that, under Texas law, "failure-to-warn claims impose a different requirement from federal law: warning consumers or prescribing physicians instead of warning the FDA."[11] As a result, Plaintiff's attempt to equate federal and state requirements in order to characterize Count II

[8] Mot. ¶ 6.

[9] *Id*. at ¶ 5.

[10] *Id*.

[11] *Bulox*, 773 F. Supp. 3d at 364; *see* Ruling at 12:2–13:4.

as a "parallel" claim necessarily fails. To the extent Plaintiff relies on Defendant's failure to communicate adverse events to physicians, consumers, or the "marketplace" to support its failure-to-warn claim, those obligations constitute additional or different requirements from those imposed under federal law. Accordingly, as the Court previously explained, Count II is preempted under *Riegel v. Medtronic, Inc*.[12]

6. Further, the specific averments Plaintiff cites to show that Defendant conveyed false information to the "marketplace" and, by proxy, to Plaintiff and his physician, demonstrate that the source of the information was the FDA's own "MAUDE" database, which published Defendant's reports for public use.[13] Hence, the allegations do not describe two separate false communications—one to the FDA and another to physicians and consumers—but, rather, rest on the same alleged false reporting to the FDA. Because Plaintiff predicates a failure-to-warn claim on this alleged reporting violation, Count II is also impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, which held that there is no private right of action for noncompliance with PMA requirements.[14]

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[12] *See* 552 U.S. 312, 330 (2008); Ruling at 5:4–8.

[13] Mot. at ¶ 5 (citing D.I. 1, Complaint ¶¶ 179–180).

[14] Ruling at 5:9–15 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)); *see also id.* at 13:20–14:4 (explaining that efforts to use state tort law to enforce the FDCA are impliedly preempted).

7. Finally, as to Count II, Plaintiff's reliance on Defendant's failure to warn the "marketplace" or the "consumer" fails under Texas's learned intermediary doctrine. This doctrine permits a manufacturer of prescription pharmaceuticals or medical devices to satisfy its duty to warn the end user by giving an adequate warning to the prescribing physician.[15] Consequently, to the extent Plaintiff's failure-to-warn claim is premised on a failure to warn the end user of the allegedly defective product, it is barred under the learned intermediary doctrine.

8. Turning to the second bases for reargument, Plaintiff contends that the Court improperly resolved Count II and Count III together, without conducting a separate analysis of the general negligence claim.[16] Specifically, Plaintiff asserts that, in doing so, the Court overlooked two distinct theories embedded within Count III—negligence *per se* and negligent manufacturing—that qualify as non-preempted parallel claims.[17] Plaintiff maintains that these theories escape preemption for the same reason Count I survived dismissal: they assert state-law

[15] *See Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 153–158 (Tex. 2012) (explaining the learned intermediary doctrine); *see also Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (holding that the learned intermediary doctrine applies in medical products liability actions in Texas).

[16] Mot. ¶ 2.

[17] *Id*. at ¶ 3.

liability arising solely from a federal-law violation without imposing any additional or different requirements.[18]

9. As to the first theory, the Court expressly addressed the negligence *per se* theory in the Ruling.[19] To reiterate, Texas law does not permit recovery under a negligence *per se* theory where there is no statutory basis for civil liability.[20] Applying this principle, Texas courts have repeatedly held that an alleged FDCA violation cannot support a negligence *per se* claim because the FDCA provides no private cause of action.[21] Consequently, applying Texas law, this Court properly rejected Plaintiff's proposed negligence *per se* claim, which is entirely premised on a violation of FDA requirements.

10. With respect to the negligent manufacturing claim, however, the Court did not specifically address that theory as distinct from the strict liability manufacturing defect claim in Count I. Upon further review, the Court finds that negligent manufacturing claims are not automatically preempted under Texas law and may proceed as parallel claims if specific violations of the applicable federal requirements are pleaded with sufficient detail and do not impose different or

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[18] *Id*.

[19] Ruling at 14:14–17 (citing *Perry v. S.N.*, 973 S.W.2d 301, 305 (Tex. 1998)).

[20] *See Perry*, 973 S.W.2d 301, 304–305 (Tex. 1998).

[21] *See e.g., Baker v. Smith & Nephew Richards, Inc.*, 1999 WL 811334, at *8 (Tex. Dist. June 7, 1999); *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002); *Monk v. Wyeth Pharm., Inc.*, 2017 WL 2063008, at *8 (W.D. Tex. May 11, 2017).

additional requirements.[22] Here, Count III is pleaded as a general negligence claim encompassing multiple embedded theories, including negligent manufacturing.[23] Because such a claim, when properly pleaded, is not preempted under Texas law, granting Plaintiff's alternative request for leave to amend so as to properly state a negligent manufacturing theory is the proper relief.

11. In response, Defendant does not identify any prejudice it would suffer from the proposed amendment, choosing instead to argue that amendment would be futile and that Plaintiff failed to adequately explain how he intends to amend.[24] Defendant is wrong on both accounts. First, as explained above, Texas law explicitly recognizes properly pleaded negligent manufacturing claims as non-preempted parallel claims; hence, the amendment is not futile. Second, Plaintiff specifically requested leave to amend to "state negligent manufacturing as a distinct count mirroring the sustained allegations of Count I[.]"[25] This sufficiently explains how the proposed amendment will survive preemption. Indeed, Defendant acknowledges as much by requesting that, if leave is granted, it should be limited to allowing Plaintiff to clarify whether he is "pursuing a

[22] *See Bass v. Stryker Corp.*, 669 F.3d 501, 515 (5th Cir. 2012) (holding that a negligence manufacturing claim arising under Texas law that was strictly based on a failure to adhere to federal regulations was not preempted).

[23] *See* Compl. ¶¶ 202, 206.

[24] Opp'n at 6.

[25] Mot. ¶ 7.

manufacturing defect in strict liability, negligence, or both."[26] The Court agrees. Accordingly, the Court grants leave to amend for the sole purpose of stating a negligent manufacturing claim, whether pleaded within the surviving Count I or as a separate count.[27] Conversely, Plaintiff's other proposed amendments—alleging Defendant's communications with physicians and consumers with further specificity and clarifying the negligence *per se* theory—would be futile for the reasons already stated.[28]

12. In sum, while reargument is unwarranted, the Court finds leave to amend the proper relief under the circumstances. Because Superior Court Civil Rule 15(a) counsels that "leave shall be freely given when justice so requires" and because Defendant fails to establish any prejudice or meritorious futility concerns, the Court grants leave to amend for the limited purpose of stating a negligent manufacturing claim.

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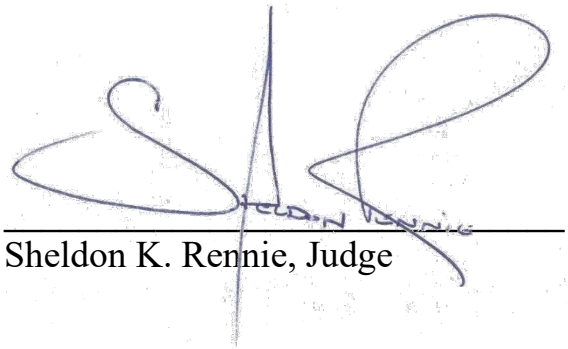
[26] Opp'n at 6.

[27] *See* Super. Ct. Civ. R. 8(e)(2) (permitting a party to set forth two or more claims in one or multiple counts).

[28] *See* Mot. ¶ 7.

NOW, THEREFORE, IT IS HEREBY ORDERED that Plaintiff's Motion for Reargument is **DENIED**, and that his alternative request for Leave to Amend the Complaint is **GRANTED**, strictly within the parameters stated above.



Sheldon K. Rennie, Judge