IN THE UNITED STATES COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CHRISTOPHER URQHART, Individually, and as Widower of NANCY JUNE URQHART, deceased, and AMY EHLERS, Individually, and as daughter of NANCY JUNE URQHART, deceased,	)	
Plaintiffs,	)	
v.	)	Case No. 4:24-cv-01465-SRC
ABIOMED, INC.,	)	
Defendant.	)	

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS

COMES NOW Christopher Urquhart and Amy Ehlers, husband and daughter of Nancy June Urquhart, deceased, hereinafter referred to as ("Plaintiffs"), by and through their attorneys, McGlynn & McGlynn and Michael L. McGlynn, and in response to "Defendant, Abiomed, Inc.'s Motion for Judgment on the Pleadings" states that they have stated a claim upon which relief can be granted in their wrongful death lawsuit filed in the Circuit Court of the City of St. Louis and removed to this Court by Defendant because the claims made by Plaintiffs in their Petition allege violations of Missouri law which mirror federal laws and regulations and are parallel to the "Medical Device Amendment" (M.D.A.) which is the Statute cited by Defendant as its justification for its claim of federal preemption.

Plaintiffs are the husband and daughter of Nancy June Urquhart, deceased, hereinafter referred to as ("Nancy June"), who died on September 12, 2022, three (3) days after Nancy June underwent an open-heart surgical procedure during which a product designed, manufactured, and

sold by the Defendant and used in this surgical procedure caused Nancy June to suffer intravascular hemolysis which caused her death.

The product, which was designed, manufactured, and sold by the Defendant, was used as a pump during Nancy June's cardiac surgery and this was the purpose for which it was manufactured. However, this product was unreasonably dangerous when sold by Defendant and as a result, it failed, causing Plaintiffs to lose their wife and mother.

Defendant claims in its Motion that the product at issue was subject to premarket approval by the "United States Food and Drug Administration" (F.D.A.) and therefore Plaintiffs' claims are preempted by federal laws. Defendant failed to inform the Court that the product at issue was found to have a defects or flaws in the manufacturing process and as a result, Defendant initiated a recall of the product. Plaintiffs' claims survive because they are based upon the fact that the product sold by the Defendant was not the product approved by the F.D.A. See In re Medtronic, Inc. 623 F. 3d 1200, 1206 (8th Cir. 2010). See citations from the F.D.A. listed below:

- Medical Device Recall Database entry: Impella 5.0 Intravascular Micro Axial Blood Pump (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=200240)
- Medical Device Recall Database entry: Impella CP Intravascular Micro Axial Blood Pump (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=200243)
- Medical Device Recall Database entry: Impella 2.5 Intravascular Micro Axial Blood Pump 005042 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=200239)
- Medical Device Recall Database entry: Impella CP with SmartAssist Intravascular Micro Axial Blood Pump (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=200244)
- Medical Device Recall Database entry: Impella LD Intravascular Micro Axial Blood Pump (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=200241)
- Medical Device Recall Database entry: Impella 5.5 with SmartAssist Intravascular Micro Axial Blood Pump (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=200242)

- Abiomed: Impella 5.5 with SmartAssist Intravascular Micro Axial Blood Pump (https://www.abiomed.com/en-us/products-and-services/impella/impella-55-with-smartassist)

> Product:
>
> "Impella 5.5 with Smart Assist intravascular micro axial blood pump, Product Numbers 0550-0008 and 1000100"
>
> - United State Food and Drug Administration
>
> Purpose of Product:
>
> "The Impella 5.5 with Smart Assist heart pump delivers full cardiac support, allowing the heart to rest and enabling the heart to achieve its natural pumping function without additional support. This heart pump is designed for long-duration support, enables patient mobility and optimizes recovery by using real-time intelligence."
>
> - Abiomed
>
> Manufacturer Reason for Recall:
>
> "There is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility."
>
> - United State Food and Drug Administration

In *Hofts v. Howmedica Osteonic Corp.*, 597 F. Supp 2d 830, 837 (S.D. Ind. 2009), The District Court concluded, upon analyzing *Riegel*, that manufacturing defect claims were not preempted by the M.D.A. (Id. At 838.) The Court explained that the Plaintiffs were basing claims on the allegations that the manufacturer failed to meet the F.D.A.'s requirements and not anything else, and that a jury "could find that [manufacturer] breached the duty of care it owed …by failing to adhere to manufacturing requirements without imposing different or additional requirements." (Id. At 837.) According to *Hofts*, the plaintiff's claims of manufacturing defect required discovery and were not subject to preemption at the pleading stage. (Id. At 838.)

Here, the Defendant is strictly liable under Missouri law because the product was manufactured in deviation from the manufacturing specifications approved by the F.D.A. and therefore Missouri law parallels federal requirements. Plaintiffs are alleging that Defendant failed to meet the F.D.A.'s requirements in its manufacturing of the product. A jury could find here that Defendant manufacturer breached the duty of care it owed to Plaintiffs by failing to adhere to manufacturing requirements. 21 U.S.C. §360 preempts only state law requirements which are different from or in addition to any requirements under that chapter. Accordingly, Plaintiffs' claims of manufacturing defect require discovery and are not subject to preemption at the pleadings stage.

Preemption is not wholesale immunity from liability. It is axiomatic that Congress did not intend to give complete protection from civil liability to medical device manufacturers for violations of federal law that injure patients. As the Supreme Court has repeatedly held, violations of state law claim that parallel federal requirements are not preempted. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 312 (2008); Lohr, 518 U.S. at 476. In pleading parallel state law claims, a plaintiff's only burden is to put forth facts that make the claim plausible on its face. See *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

Nevertheless, despite this powerful precedent allowing claims such as Plaintiffs' to proceed, Defendant attempts to persuade this Court that it should enjoy complete insulation from liability.

Plaintiffs' claims are not preempted to the extent that their claims are based on parallel state law claims that are not "different from, or in addition to" Defendants requirements. See *Reigel*, 552 U.S. at 312; and Defendant's conduct in violation of both state and federal law caused Plaintiffs' injuries.

1) Anti-Preemption Presumption

There is a "basic presumption against pre-emption." See *Bates v. Dow AgroSciences*, LLC, 544 U.S. 431, 449 (2005). Parties seeking preemption protection must overcome a considerable burden. "The presumption against preemption is heightened where federal law is said to bar state action in fields of traditional state regulation." *Reigel*, 522 U.S. at 334 (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers, Ins. Co.*, 514 U.S. 645, 655, (1995). This presumption is particularly strong in tort cases like this one because the states have historically enjoyed broad powers to protect the "lives, limbs, health, comfort, and quiet of all persons." Slaughter House Cases, 16 Wall 36, 62 (1873); see also *Connelly v. Lolab Corp.*, 927 S.W.2d 848, 851, (Mo. 1996) (en banc).

Accordingly, preemption under the M.D.A. is not unlimited. *Reigel*, 552 U.S. at 330. Rather, state law claims that are not different from, or in addition to federal law are not expressly preempted, as such duties "parallel," rather than add to, federal requirements. Id. This exception to preemption includes state law claims based on Class III devise's violation of its own premarket approval standards-precisely the case here. Id.

2) Overview: Few Preemption Holdings

In *McLaughlin v. Bayer Corp.*, 172 F. Supp.3d 804 (E.D. Pa. 2016), the Court found that

- Negative Risk Management claims are not preempted to the extent Plaintiff seeks to hold Defendant to federal risk management standards; and
- Breach of Express Warranty claims are not preempted because the claim arose from alleged contracts between the parties; and
- Negligent Misrepresentation claims are not preempted to the extent that the misrepresentations were inconsistent with F.D.A. materials; and

- Negligent Manufacturing claims are not preempted to the extent that the manufacturing differed from federal requirements; and
- Negligent Failure to warn the F.D.A. claims are not preempted because independent state law exists under Section 388 of the Restatement 2d of Torts.

See generally *McLaughlin v. Bayer Corp.*, 172 F. Supp.3d 804 (E.D. Pa. 2016) and De La Paz, 159 F. Supp 3d 1085 (N.D. Cal. 2016). (Claims for negligent training and failure to warn not preempted and leave to amend granted to plead non-preempted claims on express warranty, misrepresentation, and manufacturing defect).

"The United States Supreme Court has cautioned that in the interest of preventing federal encroachment on the state's authority, a court interpreting a federal statute pertaining to areas traditionally controlled by state law should be reluctant to find preemption." *State ex rel. Proctor v. Mesina*, 320 S.W.3d 145, 148 (Mo.2010) (citing *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 667 (1993). In finding preemption, a court must conclude that it "was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947).

3) Specific Claims are not Preempted and are Plausible

Plaintiffs' claims are not preempted. Each claim is all brought under Missouri law, which parallels federal requirements:

Theory of Liability	Federal Requirements	Missouri Law
Strict Liability	21 C.F.R. § 803.50, et seq. 21 C.F.R. § 814.82(a)(9) 21 C.F.R. § 814.39 (d)	Keener v. Dayton Elec. Mfg. Co., 445 S.W.2d 362 (Mo. 1969)
Negligent Manufacturing	21 C.F.R. § 820.20 et seq. Current Good Manufacturing Practices; 21 U.S.C. § 351(f)	Keener, 445 S.W.2d at 362; Chubb Grp. of Ins. Companies v. C.F. Murphy & Assocs., Inc. 656 S.W.2d 766, 775 (Mo. Ct. App. 1983)

Negligent Failure to Warn	21 C.F.R. § 803.50, et seq. 21 C.F.R. § 814.82(a)(9)	See Smith v. Brown & Williamson Tabacco Corp., 275 S.W.3d 748, 785 (Mo. Ct. App. 2008)
Negligent Per Se	21 C.F.R. § 803.50, et seq. 21 C.F.R. § 814.82(a)(9) 21 C.F.R. § 814.39(d) 21 C.F.R. § 820.20 et seq.	Burns v. Frontier II Properties, Ltd. P'ship, 106 S.W.3d 1, 3 (Mo. Ct. App. 2003) (citing §§ 286, 288 Restatement (Second) of Torts)
Negligent Misrepresentation	PMA conditions	Ryann Spencer Grp., Inc. v. Assurance Co. of Am., 275 S.W.3d 284, 290—91 (Mo. Ct. App. 2008)
Breach of Express Warranty	Preemption Not Applicable – Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 525 (1992).	Renaissance Leasing, LLC v. Vermeer Mtg. Co., 322 S.W.3d 112, 122 (Mo.2010)
Negligent Training	Training Guidelines Physicians' Training Manuel	§ 324A of the Restatement (Second) of Torts. See Kaplan, S.W.3d at 70.

In conclusion, Plaintiffs, husband and daughter of Nancy June Urquhart, deceased, respectfully request this Court to deny "Defendant's Motion for Judgment on the Pleadings" and allow their claims to continue through discovery for the reasons that their claims are not different from or in addition to federal law as such duties parallel rather than add to federal law requirements because Defendant's product violated its own premarket approval standards when Defendant failed to manufacture the product as it was approved. In the alternative, Plaintiffs request leave of Court to amend their Petition to fully allege this and be allowed to conduct discovery to prove this.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **"Plaintiffs' Memorandum of Law in Opposition to Defendant's Motion for Judgment on the Pleadings "** has been electronically served on counsel via the Missouri Casenet e-File system, or electronic mail, on this 3rd day of January 2025. Under penalties of perjury as provided by law, I certify that the statements in this affidavit are true.

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