

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF
OHIO, EASTERN DIVISION

Lester v. Abiomed, Inc., et al.

Lester v. Abiomed, Inc., No. 1:25 CV 1081 (N.D. Ohio 2026) · No. 1:25 CV 1081 · Decided March 31, 2026

SUMMARY

The United States District Court for the Northern District of Ohio granted Abiomed, Inc. and Johnson & Johnson’s partial motion to dismiss and motion to strike amended class allegations in a medical-device product-liability action. The court dismissed with prejudice claims for fraudulent concealment, fraudulent misrepresentation, and violations of the Ohio Consumer Sales Practices Act as abrogated by the Ohio Product Liability Act. The court also struck the proposed nationwide personal-injury class allegations because individualized issues, differing state laws, and lack of predominance and superiority defeated class treatment.

CASE DETAILS

COURT	United States District Court for the Northern District of Ohio, Eastern Division
WRITING FOR THE COURT	Patricia A. Gaughan
JURISDICTION	United States District Court for the Northern District of Ohio, Eastern Division
DECIDED	March 31, 2026
DOCKET	1:25 CV 1081
DISPOSITION	other
PROCEDURAL POSTURE	Defendants moved under Federal Rule of Civil Procedure 12 to dismiss three counts of Plaintiff's amended class-action complaint and moved to strike all class allegations. The court granted both motions.
STANDARD OF REVIEW	On a motion to dismiss, the court presumed the well-pleaded factual allegations true. For the class allegations, the court applied Federal Rule of Civil Procedure 23 and considered whether the complaint itself demonstrated that class treatment could not be maintained and discovery would not cure the defect.
PRECEDENTIAL VALUE	unpublished district court memorandum opinion; persuasive value only

PARTIES

Rebecca L. Lester, individually and as administrator of the Estate of Garry D. Lester, and all others similarly situated v. Abiomed, Inc., Johnson & Johnson, et al.

TOPICS

motions to dismiss

class actions

consumer protection

fraud

civil procedure

PRACTICE AREAS

civil procedure

product liability

consumer protection

fraud

class actions

QUESTIONS PRESENTED

1. Whether the Ohio Product Liability Act abrogated Plaintiff's fraudulent concealment, fraudulent misrepresentation, and Ohio Consumer Sales Practices Act claims because they were based on alleged defects and failure-to-warn conduct involving the medical devices.
2. Whether the fraud claims independently failed under Federal Rule of Civil Procedure 9(b) for failure to plead reliance and the who, what, when, where, and how of the alleged concealment or misrepresentation.
3. Whether the Ohio Consumer Sales Practices Act claim was unavailable because the complaint sought damages for personal injury or death and failed to plead reliance or proximate cause.
4. Whether the proposed nationwide personal-injury and product-liability class failed the predominance and superiority requirements of Federal Rule of Civil Procedure 23(b)(3), such that the class allegations should be stricken before discovery.

HOLDINGS

1. The Ohio Product Liability Act abrogates Plaintiff's fraudulent concealment and fraudulent misrepresentation claims because the claims are substantively failure-to-warn product-liability claims, notwithstanding their fraud labels.
2. The Ohio Consumer Sales Practices Act claim was abrogated by the OPLA because it was primarily rooted in product-liability allegations concerning the safety and defects of the devices; it also failed because the complaint sought damages for personal injury or death and did not adequately plead reliance or proximate cause.
3. Even if the fraud claims were not abrogated by the OPLA, they would be dismissed because Plaintiff failed to plead reliance and failed to identify with particularity the alleged concealment or misrepresentation.
4. The proposed nationwide personal-injury and product-liability class failed the predominance requirement because individualized questions concerning defects, causation, medical histories, warnings, defenses, and applicable state law overwhelmingly predominated over common questions.

5. The proposed class failed the superiority requirement because the individualized inquiries and differing legal standards made a class action an inferior method of adjudication.

KEY QUOTATIONS

“A court may strike class action allegations prior to a motion for class certification where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met and where discovery would not alter the central defect in the class claim.” (8)

“A failure on either front dooms the class.” (8)

“No one set of operative facts establishes liability because liability as to each class member will involve highly individualized inquiries.” (11)

“Taken together, it is clear that the individual issues of class members, requiring individualized proof, overwhelmingly outweigh any common issues subject to generalized proof and applicable to the whole class.” (13)

FACTUAL BACKGROUND

Abiomed manufactured Impella Class III medical devices approved by the FDA for use during coronary procedures. Plaintiff alleged that the devices could perforate heart ventricles and surrounding tissue, that Defendants concealed adverse-event information, and that a device used during Garry Lester's May 2021 procedure caused a perforation leading to complications and his death. Plaintiff later filed an individual and class action involving persons nationwide who allegedly suffered ventricular perforations or cardiovascular injuries from the devices.

PROCEDURAL HISTORY

Plaintiff filed an amended class-action complaint asserting ten claims arising from injuries allegedly caused by an Impella medical device. Defendants sought dismissal of the fraudulent concealment, fraudulent misrepresentation, and Ohio Consumer Sales Practices Act claims, arguing that they were abrogated by the Ohio Product Liability Act, and also sought to strike the class allegations. The court dismissed Counts V, VI, and VII with prejudice, struck the class allegations, and allowed the action to proceed on Counts I-IV and VIII-X on an individual basis.

DISPOSITION

other

CASES CITED

- *Wimbush v. Wyeth*, 619 F.3d 632, 639 (6th Cir. 2010)
- *Evans v. Hanger Prosthetics & Orthotics, Inc.*, 735 F. Supp. 2d 785, 795-96 (N.D. Ohio 2010)
- *Flex Homes, Inc. v. Ritz-Craft Corp. of Mich., Inc.*, 2009 WL 3242140, at *13 n.22 (N.D. Ohio Sept. 30, 2009)

- Muncie Power Prod., Inc. v. United Techs. Auto., 328 F.3d 870, 873 (6th Cir. 2003)
- McKinney v. Microsoft Corp., 2011 WL 13228141, at *7 (S.D. Ohio May 12, 2011)
- Mitchell v. Proctor & Gamble, 2010 WL 728222, at *4 (S.D. Ohio Mar. 1, 2010)
- Perry v. Ethicon, Inc., 2022 WL 912214, at *3 (S.D. Ohio Mar. 29, 2022)
- Everhart v. Merrick Mfg. II, LLC, 204 N.E.3d 620, 638 (Ohio Ct. App. 2022)
- Hogue v. Pfizer, 893 F. Supp. 2d 914, 918 (S.D. Ohio 2012)
- Stratford v. SmithKline Beecham Corp., 2008 WL 2491965, at *8 (S.D. Ohio June 17, 2008)
- Smith v. Gen. Motors LLC, 988 F.3d 873, 884 (6th Cir. 2021)
- Pilgrim v. Universal Health Card, LLC, 660 F.3d 943, 945-49 (6th Cir. 2011)
- Speerly v. Gen. Motors, 143 F.4th 306, 316-18, 321 (6th Cir. 2025)
- Doster v. Kendall, 54 F.4th 398, 430-31 (6th Cir. 2022)
- Tyson Foods, Inc. v. Bouaphakeo, 577 U.S. 442, 453 (2016)
- In re Nissan N. Am., Inc. Litig., 122 F.4th 239, 252 (6th Cir. 2024)
- In re Am. Med. Sys., Inc., 75 F.3d 1069, 1084-85 (6th Cir. 1996)
- Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 351 n.6 (2011)
- Young v. Nationwide Mut. Ins., 693 F.3d 532, 545 (6th Cir. 2012)
- Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 625 (1997)
- Colley v. Procter & Gamble Co., 2016 WL 5791658, at *3 (S.D. Ohio Oct. 4, 2016)
- Durocher v. NCAA, 2015 WL 1505675, at *10 (S.D. Ind. Mar. 31, 2015)
- Ehlers v. Abiomed, Inc., 792 F. Supp. 3d 941 (E.D. Mo. 2025)

OPINION

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION Rebecca L. Lester, and all others similarly) CASE NO. 1:25 CV 1081 situated; individually and as administrator) of the Estate of Deceased Garry D. Lester,)) Plaintiffs,) JUDGE PATRICIA A. GAUGHAN) vs.)) Abiomed, Inc., et al.,)) Memorandum of Opinion and Order) Defendants.) INTRODUCTION This matter is before the Court upon defendant Abiomed, Inc. and defendant Johnson & Johnson's Partial Motion to Dismiss Plaintiff's Amended Complaint and Motion to Strike Plaintiff's Amended Class Allegations.

This is a product liability case. For the reasons that follow, defendants' Partial Motion to Dismiss Plaintiff's Amended Complaint is GRANTED and defendants' Motion to Strike Plaintiff's Amended Class Allegations is GRANTED. BACKGROUND For purposes of ruling on the pending motion to dismiss, all well-plead factual allegations in plaintiff's Amended Class Action Complaint (Doc.

20) are presumed true. Defendant Abiomed, Inc., which was acquired by defendant Johnson & Johnson in 2022 (together, "Defendants"1), manufactures assistive medical devices known as Impella blood pumps (the "Devices").

The Devices are Class III medical devices approved by the U.S. Food and Drug Administration (“FDA”) to assist the circulation of blood during coronary procedures. On December 5, 2016, the FDA granted premarket approval for the Devices, expanding the indications to include high-risk percutaneous coronary intervention (“PCI”) and cardiogenic shock. Soon after approval from the FDA for expanded use of the Devices for left ventricle high-risk PCI procedures, healthcare providers sent Defendants Adverse Event Reports (“AERs”).

As early as 2018, Defendants were aware that the Devices were perforating the ventricles of persons’ hearts and surrounding vessels and cardiovascular tissue. Despite knowledge of these AERs, Defendants concealed this information from the FDA and the public. Defendants allegedly concealed some 1,793 deaths and 6,573 serious injury AERs between December 2016 and September 2021.

On or about May 27, 2021, Garry D. Lester (“Decedent”) had a Device placed into his left ventricle. Shortly after placement, Decedent became hypotensive. It was later determined that Decedent’s ventricle had been perforated, resulting in several, significant complications that led to Decedent’s serious injury and death on May 30, 2021.

In October 2021, Defendants issued a “Technical Bulletin” (“Bulletin”) to Abiomed Inc.’s sales force/representatives. The Bulletin made recommendations for avoiding left ventricle perforations with the Devices. Despite its issuance, the Bulletin was not universally known because 1 Although many of the events underlying this dispute occurred before Johnson & Johnson acquired Abiomed, Inc. in 2022, this Court generally attributes all actions to “Defendants” for purposes of resolving these motions.

2 Defendants did not alert the FDA of the revised guidance in the Bulletin, did not issue a recall, and did not update the instructions that were provided to customers when the Devices were sold. On March 1, 2023, the FDA visited Abiomed Inc.’s corporate offices to investigate complaints related to the Devices.

The FDA’s investigation at Abiomed Inc.’s offices found certain Devices were adulterated, defectively manufactured and designed, nonconforming, and lacked sufficient warnings. The FDA then issued a Warning Letter on September 19, 2023.

On December 27, 2023, Defendants initiated a recall for the Devices, specifically the Instructions for Use, which was posted on February 9, 2024, and the FDA reported to the public on March 21, 2024. On September 16, 2024, Plaintiff Rebecca Lester (“Plaintiff”) was informed by a competent licensed medical physician that a defective Device used in Decedent’s procedure most likely caused the left ventricle perforation that led to his death.

Thereafter, Plaintiff filed suit against Defendants individually and as the administrator of the estate of Garry D. Lester, on behalf of herself, the estate, next of kin, and all others similarly situated.

Plaintiff names the class as: All individuals and their respective estates/representatives who, until the date that notice is mailed to the Class, had a[Device] inserted into their heart while under the care of a physician in the State of Ohio, and any other state in the United States, and who suffered a ventricular perforation and/or cardiovascular injuries, resulting in serious injury or death between January 1, 2018 and March 21, 2024.

(Doc. 20 ¶ 117.) ANALYSIS Through their instant motions, Defendants move to dismiss certain claims in Plaintiff's Amended Complaint and strike all the class allegations. Plaintiff opposes both motions. The Court will address each in turn. 3 A. Defendants' Partial Motion to Dismiss Defendants move to dismiss three of the ten claims raised in the Amended Complaint: Count V (Fraudulent Concealment), Count VI (Fraudulent Misrepresentation), and Count VII (Ohio's Consumer Sales Practices Act ("OCSPA")).

Defendants contend that these three claims are abrogated by the Ohio Product Liability Act ("OPLA").² The OPLA, codified at Ohio Revised Code §§ 2307.71 to 2307.80, "explicitly eliminate[s] 'all common law product liability claims or causes of action.'" *Wimbush v. Wyeth*, 619 F.3d 632, 639 (6th Cir. 2010) (quoting Ohio Rev. Code § 2307.71(B)); *Evans v. Hanger Prosthetics & Orthotics, Inc.*, 735 F. Supp. 2d 785, 795–96 (N.D.

Ohio 2010) ("[W]hen the Ohio General Assembly enacted the current version of the OPLA, which became effective on April 7, 2005, it abrogated all common law claims relating to product liability causes of actions." (citing *Flex Homes, Inc. v. Ritz–Craft Corp. of Mich., Inc.*, 2009 WL 3242140, at *13 n.22 (N.D. Ohio Sept. 30, 2009))).

Thus, in Ohio, all "product liability claims" must be brought pursuant to the OPLA. The OPLA defines a "product liability claim" as one "that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question" allegedly resulting from "the design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product," "[a]ny warning or instruction, or lack of warning or instruction, associated with 2 By relying on cases applying Ohio law, the parties implicitly acknowledge that Ohio law governs this diversity action.

See, e.g., *Muncie Power Prod., Inc. v. United Techs. Auto.*, 328 F.3d 870, 873 (6th Cir. 2003) (summarizing that, where Ohio is the forum state, federal courts sitting in diversity apply a balancing test which presumes that "the law of the place where the injury occurs will be applied to a tort action" unless "another state has a more significant relationship to the action.").

4 that product," or "[a]ny failure of that product to conform to any relevant representation or warranty." Ohio Rev. Code § 2307.71(A)(13). "Considering this statutory language, courts have

routinely dismissed non-statutory product–liability claims brought under Ohio law.” *McKinney v. Microsoft Corp.*, 2011 WL 13228141, at *7 (S.D. Ohio. May 12, 2011) (collecting cases).

This includes common law claims for fraud, and claims brought under the OCSA that “are primarily rooted in product liability claims.” *Mitchell v. Proctor & Gamble*, 2010 WL 728222, at *4 (S.D. Ohio Mar. 1, 2010). Here, Defendants contend that “Plaintiff’s fraudulent concealment, fraudulent misrepresentation, and OCSA claims are based on the same allegations as her products liability claims.” (Doc.

23, at 5.) Accordingly, “[t]he plain text of the OPLA abrogates Plaintiff’s fraud and consumer protection claims, which are merely products liability claims masquerading as common law claims.” (*Id.*) This Court agrees with Defendants.

First, Plaintiff’s Count V (Fraudulent Concealment) and Count VI (Fraudulent Misrepresentation) rest on allegations that Defendants knew about defects concerning the Devices but concealed and/or misrepresented the safety of the Devices. (E.g., Doc. 20 ¶¶ 200, 212.) Plaintiff maintains that these allegations go beyond product liability and seek redress for Defendants’ general common law duty not to deceive.

After careful review of the Amended Complaint, however, this Court is not convinced. The allegations in Counts V and VI are not framed as claims grounded in the general duty not to deceive. Rather, the allegations are intrinsically intertwined with those of Plaintiff’s product liability claims.

The allegations in Counts V and VI focus on Defendants’ failure to tell users about a particular issue with the Devices that, in turn, resulted in personal injuries to Plaintiff, Decedent, 5 and others. Cf. *Perry v. Ethicon, Inc.*, 2022 WL 912214, at *3 (S.D. Ohio Mar. 29, 2022) (“Claims that otherwise fall within the ambit of the OPLA, for instance, are not considered ‘product liability claims’ if they do not pursue ‘compensatory damages’ for ‘Harm’ that arises from a codified product defect.”).³ To be sure, as Defendants point out, the allegations supporting the frauds claims are nearly identical to the allegations supporting the product liability claims.

(Doc. 31, at 11–13 (charting the overlapping language between the claims).) *Perry*, 2022 WL 912214, at *3 (“Courts consider a common law claim to constitute a product liability claim—and, thus, to be abrogated by the OPLA—when [t]he actionable conduct that forms the basis of that claim is the same conduct that the OPLA defines as giving rise to a product liability claim.” (quoting *Mitchell*, 2010 WL 728222, at *4) (internal quotation marks omitted)).

Altogether, Counts V and VI—no matter how they are labeled—read as claims for failure to warn, not claims of fraud.⁴ See *Everhart v. Merrick Mfg. II, LLC*, 204 N.E.3d 620, 638 (Ohio Ct. 3 Plaintiff does generally allege “economic damages,” but the actual factual allegations allude only to damages from personal injuries caused by the Devices’ defects. ⁴ To this point, even if Counts

V and VI were not abrogated by the OPLA, they would still fail because Plaintiff has not plead any facts sufficient to allege the reliance element of these claims under Ohio law.

At most, Plaintiff pleads that “Decedent, Class members, Class members’ Decedents and their physicians relied upon the representations and were unaware of the substantial risks of the [Devices] which the Defendant(s) concealed from the public, including Plaintiff, Decedent, Class members, Class members’ Decedents, and their physicians.” (Doc. 20 ¶ 205; see also id. ¶ 112 (“In reliance on [Defendants’] representations, Decedent’s doctors were induced to, and did use, the [Device].”).

This conclusory allegation is insufficient to support Plaintiff’s claims of fraud. Further, while Plaintiff generally alleges that Defendants misrepresented or concealed the Devices’ safety through advertisements and marketing, she never alleges that she, Decedent, Class members, Class members’ Decedents, and/or their physicians saw and relied on these materials.

Because Plaintiff fails to factually allege that she, or anyone else, ever relied on any specific misrepresentation or concealment by Defendants concerning the Devices, any fraud claims not abrogated by the OPLA would still be dismissed. See Fed. R. Civ. P. 9(b); *Smith v. Gen. Motors LLC*, 988 F.3d 873, 884 (6th Cir. 2021) (“Rule 9(b) imposes a heightened pleading requirement for 6 App.

2022) (“The essential nature of the substantive allegations of the plaintiff’s claim, not the artificial label attached to the claim, determines the claim’s true nature.” (internal quotation marks and citation omitted)). While “the OPLA does not abrogate fraud claims which are based on a general duty not to actively deceive... the OPLA does abrogate fraud claims arising from a duty to warn.” *Hogue v. Pfizer*, 893 F. Supp. 2d 914, 918 (S.D.

Ohio 2012), vacated on other grounds, 2013 WL 12368615 (S.D. Ohio Sept. 5, 2013) (citing *Stratford v. SmithKline Beecham Corp.*, 2008 WL 2491965, at *8 (S.D. Ohio June 17, 2008) (further citation omitted)). Plaintiff’s allegations that Defendants concealed and/ or misrepresented facts is essentially a claim for failure to warn about the Devices’ defects. *Stratford*, 2008 WL 2491965 at *8 (holding that allegations of fraudulent omissions were “essentially allegations that [Defendant] failed to properly warn physicians and consumers of the risk” and were thus preempted by the OPLA).

Thus, Plaintiff’s claims that Defendants concealed and/or misrepresented information about the Devices’ safety arise from a failure to warn and are abrogated by the OPLA. Similarly, Count VII (OCSPA) rests on allegations that Defendants knew about defects concerning the Devices but concealed and/or misrepresented the safety of the Devices. While Plaintiff contends that the OCSPA claim is “entirely discrete from the underlying product liability claims” (Doc.

29, at 9), a review of Count VII's allegations reveals otherwise. Like Counts V and VI, Count VII focuses on representations concerning the safety of the Devices given a specific defect concerning cardiac/cardiovascular perforation.

Thus, like the fraud claims alleging fraud. That means that parties bringing a fraudulent concealment claim must specify the who, what, when, where, and how of the alleged omission. And they must do so with particularity.” (internal quotation marks and citations omitted)). 7 claims, Count VII is intrinsically intertwined with those of the product liability claims.

To be sure, Count VII's allegations, like the fraud claims, are nearly identical to the allegations supporting the product liability claims. (Doc. 31, at 15–16 (charting materially similar language between OCSPA allegations and OPLA allegations).) Further, the OCSPA does not apply to cases seeking damages for personal injuries. See Ohio Rev. Code § 1345.12(C) (“Section 1345.01 to 1345.13 of the Revised Code do not apply to... [c]laims for personal injury or death.”).

As mentioned above, Plaintiff does generally allege “economic damages,” but the actual factual allegations allude only to damages from personal injuries caused by the Devices' defects. See Mitchell, 2010 WL 728222, at *4 (holding that a plaintiff “can not separate out his claims from the purview of the OPLA simply by claiming only economic losses”). Clearly, Count VII is “primarily rooted in product liability claims” and abrogated by the OPLA.

Id.; see also Schnell v. Am. Home Prod. Corp., 2000 WL 35777837, at *1 (N.D. Ohio July 11, 2000) (concluding that the plaintiff's claims under the OCSPA were “encompassed under the statutory framework of the [OPLA]” because they alleged “representations[s] of a material fact concerning the character, quality, or safety of a product.”).⁵ Further, even if Plaintiff's OCSPA claim was not abrogated by the OPLA, it would still be dismissed because, as discussed above, Plaintiff has failed to plead sufficient factual allegations suggesting that she, Decedent, any class members, and class members' Decedents, or any of the physicians for those individuals relied on any false statement from Defendants, which impacted their decision to purchase the Devices.

Temple v. Fleetwood Enters., Inc., 133 F. App'x 254, 265 (6th Cir. 2005) (finding that the OCSPA requires a plaintiff to prove a material misrepresentation or omission “impacted his decision to purchase the item at issue”); see also Reeves v. PharmaJet, Inc., 846 F. Supp. 2d 791, 798 (N.D. Ohio 2012) (dismissing an OCSPA claim because the plaintiff “d[id] not allege that he saw or was even aware of any alleged misrepresentations regarding the PharmaJet injector” before receiving treatment, and thus “fail[ed] to allege the elements of reliance or proximate cause which are necessary to state a claim under the OCSPA”).

⁸ For all the aforementioned reasons, Counts V, VI, and VII are abrogated by the OPLA and are dismissed with prejudice because Plaintiff failed to cure these deficiencies through her amended allegations and any further amendment of these claims would be futile. B. Defendants' Motion to

Strike Class Allegations When a person initiates a class action lawsuit, “[a]t an early practicable time... the court must determine by order whether to certify the action as a class action” Fed.

R. Civ. P. 23(c)(1)(A); see also LR 23.1(c) (“As soon as practicable after the motion papers for and against class action determination have been submitted, the Court shall enter an order determining whether the action shall be so maintained. Nothing in this Rule shall preclude any party from moving to strike the class action allegations.”). A court may strike class action allegations prior to a motion for class certification where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met and where discovery would not alter the central defect in the class claim.

Pilgrim v. Universal Health Card, LLC, 660 F.3d 943, 945 (6th Cir. 2011) (“That the motion to strike came before the plaintiffs had filed a motion to certify the class does not by itself make the court’s decision reversibly premature.... [W]e cannot see how discovery or for that matter more time would have helped [plaintiffs].... Their claims are governed by different States’ laws, a largely legal determination, and no proffered or potential factual development offers any hope of altering that conclusion, one that generally will preclude class certification.”).

A plaintiff seeking to bring a class action must satisfy Rules 23(a) and (b). Under Rule 23(a), the class must establish four requirements: numerosity, commonality, typicality, and adequate representation. For classes certified under Rule 23(b)(3), like this one,⁶ a plaintiff must show “that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” “A failure on either front dooms the class.” *Pilgrim*, 660 F.3d at 946.

Even if Plaintiff could satisfy all four requirements under Rule 23(a),⁷ it is clear from the allegations in the Amended Complaint that she cannot establish Rule 23(b)(3)’s predominance. Plaintiff fails to cite the portion or portions of Rule 23 under which it is claimed that the suit is properly maintainable as a class action. See LR 23.1(b)(A). She does, however, reference the standards for maintaining a class action under Rule 23(b)(3).

Accordingly, the Court considers her allegations under that subsection.⁷ Although the Court need not reach a determination as to the Rule 23(a) factors, the Court notes that Plaintiff likely could not satisfy all four.

For instance, to meet Rule 23(a)’s “commonality” requirement, “[t]he decisionmaker must be able to resolve the question with ‘a yes-or-no answer for the class in one stroke.’” *Speerly v. Gen. Motors*, 143 F.4th 306, 316 (6th Cir. 2025) (quoting *Doster v. Kendall*, 54 F.4th 398, 430–31 (6th Cir. 2022), vacated as moot, 144 S. Ct. 481 (2023) (quotation omitted)).

A question is not common if the answer requires “evidence that varies from member to member.” *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (quotation marks omitted). Here, even without undertaking the rigorous claim-by-claim review expected to determine whether there is a common question of law or fact, the very nature of plaintiff’s personal injury and product liability claims prevents a decisionmaker from being able to resolve the question with “a yes-or-no answer for the class in one stroke.” *Doster*, 54 F.4th at 430–31.

To be sure, Plaintiff points to four potential common questions in her opposition brief. (Doc. 30, at 19.) By Plaintiff’s own allegations and definition of the class, none of these questions can be answered with a yes-or-no answer for the class in one stroke because Plaintiff does not allege that the Devices possessed the same defect. Even more fundamentally, such generalized questions do not suffice to establish the commonality requirement in the Sixth Circuit.

See *Speerly*, 143 F.4th at 318 (“The district court reasoned that ‘three readily discernible common questions that are crucial to the pleaded causes of action’ exist: whether the transmissions have shift and shudder defects; whether GM knew about them; and whether the defects are material.... With respect, that does not suffice. A court may not simply ask whether generalized questions yield a common answer.

That would undermine the bedrock principle that courts must identify common questions with respect to concrete elements of each 10 requirement. “To meet the predominance requirement, a plaintiff must establish that issues subject to generalized proof and applicable to the class as a whole predominate over those issues that are subject to only individualized proof.” *Randleman v. Fidelity Nat.*

Title Ins. Co., 646 F.3d 347, 352–53 (6th Cir. 2011). The Sixth Circuit has instructed a district court weighing the predominance requirement to “‘put the common issues on one side, the individual issues on the other, then qualitatively evaluate which side predominates.’” *Speerly*, 143 F.4th at 317 (quoting *In re Nissan N. Am., Inc. Litig.*, 122 F.4th 239, 252 (6th Cir.

2024) (further quotation omitted)). “If adding or subtracting plaintiffs from the class substantially varies the ‘substance or quantity of evidence offered’ and the cost of doing so,... the individualized questions likely overwhelm the common ones.” *Id.* (citations omitted).

Here, Plaintiff’s claims by their very nature are fact intensive and state-law specific. “No one set of operative facts establishes liability” because liability as to each class member will involve highly individualized inquiries.

In re Am. Med. Sys., 75 F.3d 1069, 1084–85 (6th Cir. 1996) (“In products liability actions... individual issues may outnumber common issues. No single happening or accident occurs to cause similar types of physical harm or property damage. No one set of operative facts establishes

liability. No single proximate cause applies equally to each potential class member and each defendant.

Furthermore, the alleged tortfeasor's affirmative defenses (such as failure to follow directions, assumption of the risk, contributory negligence, and the statute of limitations) may depend on facts peculiar to each plaintiff's case." (citation omitted)). claim. By hitching all 59 claims to a question about 'defect' in the abstract, the court overlooked how significant differences across each cause of action raise serious commonality concerns." (citations omitted).)

11 First, Plaintiff does not allege that the Devices possessed the same defect. Rather, Plaintiff alleges three different types of defects (burrs from manufacturing defects, software defects, and warning defects). See *Speerly*, 143 F.4th at 321 ("[T]his class action presents two theories of defect, each with multiple moving parts, exponentially increasing these challenges [to efficiency under Rule 23(b)(3)].").

Accordingly, the Court would have to review individualized evidence to determine whether one of three given defects actually affected the specific Device used for each class member. But even if every Device was affected by the same defect(s), liability as to each class member would still involve highly individualized inquiries, such whether the defect was the cause of that class member's injuries—which itself involves inquiries into each class member's individual medical history, conditions, medical procedures, and other potentially relevant contributory factors unique to each individual class member.⁸ Even more, Plaintiff's proposed class includes persons who used Devices after Defendants issued a recall of the Devices with revised instructions.

This further erodes any common questions among class members because some class members seemingly had access to the very "warnings" that Defendants allegedly improperly concealed from other class members. Further still, because Plaintiff seeks to represent a nationwide class, these already individualized issues become more individualized depending on which state law applies to various class members' claims and injuries.

Pilgrim, 660 F.3d at 946 (noting one reason for affirming the ⁸ For the reasons stated above, Plaintiff's fraud claims are abrogated under Ohio law and dismissed. But even if they were not, these claims only create even more individualized inquiries as the Court would have to determine whether they justifiably relied on Defendants' alleged misrepresentations or concealed facts.

See *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 351 n.6 (2011) (holding that reliance typically creates "an insuperable barrier to class certification"). ¹² district court's order finding that a nationwide class could not satisfy predominance requirement was because "different laws would govern the class members' claims").

As Defendants point out, the relevant laws governing the claims here differ considerably across the country.⁹ The Sixth Circuit has explained, "[i]f more than a few of the laws of the fifty states

differ, the district judge would face an impossible task of instructing a jury on the relevant law.” In *re Am. Med. Sys., Inc.*, 75 F.3d at 1085; see also *Pilgrim*, 660 F.3d at 948–49 (collecting cases for the proposition that differences in state laws cut strongly against nationwide classes).¹⁰ Taken together, it is clear that the individual issues of class members, requiring individualized proof, overwhelmingly outweigh any common issues subject to generalized proof and applicable to the whole class.¹¹ 9 For example, Defendants summarize that “states have implemented at least four different legal tests to determine the existence of a design defect....

Additionally, “[s]ome states require a jury to determine whether a safer alternative design existed,” but others “exclude consideration of whether a safer alternative design existed.” (Doc. 25, at 23 (citations omitted).)

Thus, as Defendants aptly point out, “[a] trial under Plaintiff’s proposed class definition would put the Court in the untenable position of both requiring the jury to consider the existence of a safer alternative design while simultaneously prohibiting the jury from considering the very same evidence.” (Id. at 23–24.) Plaintiff does not contend that Defendants’ survey of the law across the country is incorrect.

¹⁰ For this reason, the Court is not persuaded by Plaintiff’s position that the Court should allow the nationwide class allegations to proceed through discovery because, in the end, the final class may not include all 50 states. Plaintiff is the master of her complaint, and she chose to allege an untenable nationwide class. Even so, a class spanning even a few states with differing laws would face this same flaw.

Cf. *Ehlers v. Abiomed, Inc.*, 792 F. Supp. 3d 941 (E.D. Mo. 2025) (dismissing similar individual suit brought for injury caused by the Devices in Missouri). ¹¹ For similar reasons, Plaintiff is unable to satisfy Rule 23(b)’s superiority requirement. See *Young v. Nationwide Mut. Ins.*, 693 F.3d 532, 545 (6th Cir. 2012) (“Where many individual inquiries are necessary, a class action is not a superior form of adjudication.”).

Further, Rule 23(b)(3) lists four factors courts should consider in determining superiority: (1) the class members’ interests in individually controlling the prosecution or defense of separate actions; (2) the extent and nature of any litigation concerning the controversy already begun by or against class members; (3) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (4) ¹³ Given all this, it is not surprising that the Supreme Court has held that personal injury and product liability claims “are inherently unsuited for class treatment because they are ‘likely to present “significant questions, not only of damages but of liability and defenses of liability... affecting the [individual class members] in different ways.”’” *Colley v. Procter & Gamble Co.*, 2016 WL 5791658, at *3 (S.D.

Ohio Oct. 4, 2016) (quoting *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997) (quoting Fed. R. Civ. P. 23, Advisory Committee Notes to 1966 Amendment and affirming a circuit court's rejection of a "sprawling" nationwide class of personal injury product liability claims, and requiring "caution" when considering class certification of mass torts))).

In fact, "no federal appellate court has approved a nationwide personal injury, product liability or medical monitoring class." *Durocher v. NCAA*, 2015 WL 1505675, at *10 (S.D. Ind. Mar. 31, 2015) (collecting cases and granting a motion to strike personal injury class allegations). Plaintiff seemingly chooses to ignore this reality. She does not address this case law in her opposition brief to Defendants' motion.

Instead, she implores this Court to wait until after discovery has been conducted to dispose of her class allegations. This Court sees no reason to wait. Given the case law in this circuit, no amount of discovery could rectify Plaintiff's inability to satisfy Rule 23(b)(3)'s predominance requirement. the likely difficulties in managing a class action.

For reasons already discussed elsewhere in this Memorandum and Opinion, each of these factors points against the superiority of a class action here. 14 CONCLUSION For all the aforementioned reasons, Defendants' Partial Motion to Dismiss Plaintiff's Amended Complaint is GRANTED. Counts V, VI, and VII of the Amended Complaint are dismissed with prejudice. Additionally, Defendants' Motion to Strike Plaintiff's Amended Class Allegations is GRANTED.

This case will proceed on Counts I–IV and VIII–X with plaintiff Rebecca Lester individually and as administrator of the Estate of Garry Lester. IT IS SO ORDERED. PATRICIA A. GAUGHAN
United States District Judge Date: 3/31/26 15