[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 19-13380

D.C. Docket No. 1:17-cv-03181-SCJ

WENDY SHARP,
Individually and as administrator of the
estate of Estate of Milton Sharp,

Plaintiff-Appellant,

versus

ST. JUDE MEDICAL, S.C., INC.,
ST. JUDE MEDICAL, INC.,
PACESETTER, INC.,
d.b.a. St. Jude Medical Cardiac Rhythm Management Division,
ST. JUDE MEDICAL, LLC,
ABBOTT LABORATORIES,

Defendants-Appellees.

Appeal from the United States District Court
for the Northern District of Georgia

(December 23, 2020)

Before WILSON, NEWSOM, and ANDERSON, Circuit Judges.

WILSON, Circuit Judge:

Wendy Sharp appeals the district court's dismissal of her case against St. Jude Medical for failure to state a claim.[1] Ms. Sharp brought negligence and strict liability manufacturing defect claims, among others, under Georgia law. Ms. Sharp sues individually and as the personal representative of the estate of Milton Sharp, her late husband.

Mr. Sharp had a heart condition and relied on an implantable cardiac defibrillator (ICD) manufactured by St. Jude Medical to monitor and regulate his heartrate. ICDs are implanted under the skin of the chest wall; the device's power source (a pulse generator) connects to the heart through a lead (a wire that transmits electrical impulses from the generator). The lead monitors the heart rhythm and delivers an electric shock to the heart to restore its normal rhythm when an arrhythmia is detected.

On August 23, 2015, Mr. Sharp died after suffering a ventricular fibrillation. The claims against St. Jude Medical relate to the operation (or failure to operate) of Mr. Sharp's ICD. After careful consideration, and with the benefit of oral argument, we determine that Ms. Sharp pleaded enough facts to plausibly support

[1] Ms. Sharp brought claims against St. Jude Medical, Inc., St. Jude Medical S.C., Inc., Pacesetter, Inc. d.b.a. St. Jude Medical Cardiac Rhythm Management Division, and St. Jude Medical LLC. Throughout this opinion they are collectively referred to as "St. Jude Medical" or "Defendants."

her negligence and strict liability claims. We reverse the district court's dismissal of those claims.

I.

A. Procedural History

On August 22, 2017, Ms. Sharp filed a complaint against St. Jude Medical in the Northern District of Georgia for the wrongful death of her husband. The complaint alleged negligence, negligence per se, strict liability, and failure to warn. Ms. Sharp filed her First Amended Complaint on September 7, 2017 and Defendants moved to dismiss. Ms. Sharp was granted leave to amend and filed her Second Amended Complaint on September 14, 2018, alleging that Mr. Sharp's device failed because of manufacturing defects.

Specifically, Ms. Sharp alleged that defects caused the insulation around the lead to erode, thereby exposing the conductive wire. Erosion of the lead—called lead abrasion—can cause short circuiting and prevent delivery of high voltage therapy. Ms. Sharp stated that her claims arose out of Defendants' violation of FDA regulations and policies applicable to the manufacture and sale of the device.

Defendants again moved to dismiss Ms. Sharp's complaint, asserting that federal law preempted her claims and that she failed to state a claim under state law. The district court granted Defendants' motion to dismiss on August 14, 2019, finding that Ms. Sharp failed to state any claim and that her claims were

preempted.[2] This appeal followed. Though the district court dismissed all claims, Ms. Sharp appeals only the dismissal of her negligence and strict liability manufacturing defect claims.

B. Standard of Review

We review de novo a dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *Echols v. Lawton*, 913 F.3d 1313, 1319 (11th Cir. 2019). We must reverse the dismissal if the complaint "state[s] a claim to relief that is plausible on its face," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), after we accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the claimant. *See Spanish Broad. Sys. of Fla., Inc. v. Clear Channel Commc'ns, Inc.*, 376 F.3d 1065, 1070 (11th Cir. 2004). We review de novo the district court's interpretation of state law. *Tampa Bay Water v. HDR Eng'g, Inc.*, 731 F.3d 1171, 1177 (11th Cir. 2013).

[2] The district court noted that Ms. Sharp's failure to state a claim was determinative of the case, but that the court considered Defendants' preemption arguments "in the interest of caution." Because preemption is a principle derived from the Supremacy Clause, U.S. Const. Art. VI, cl. 2, it was inappropriate for the district court to reach preemption after finding that the state law claims were not viable. *See Godelia v. Doe 1*, 881 F.3d 1309, 1317 (11th Cir. 2018). Accordingly, the district court's preemption analysis was not determinative, and we need reverse today only on the question of whether Ms. Sharp stated a claim. Though not determinative, the district court's preemption analysis is flawed, nonetheless. Our precedent in *Mink v. Smith & Nephew, In*c., 860 F.3d 1319, 1327 (11th Cir. 2017) and *Godelia*, 881 F.3d at 1317, 1319–20, clearly allows for parallel claims that fit in the "narrow gap" of cases that avoid both express and implied preemption. That precedent should govern any preemption analysis of these claims.

II.

A. Factual Allegations

Ms. Sharp appeals the dismissal of two claims based on a manufacturing defect: strict products liability and negligence. She argues that she adequately stated claims for each of these causes of action in her Second Amended Complaint. Because we are reviewing the district court's ruling based on the pleadings, we accept the factual allegations in the complaint as true and construe them in the light most favorable to the plaintiff. *See Hill v. White*, 321 F.3d 1334, 1335 (11th Cir. 2003) (per curiam). Accordingly, our account of the facts comes from Ms. Sharp's Second Amended Complaint.

Mr. Sharp suffered from tachycardia, a serious heart condition involving an irregular heartbeat. Patients with potentially fatal heart rhythms commonly receive ICDs when medication cannot adequately control their condition. ICDs are Class III medical devices—the highest category of risk—and are regulated by the Food and Drug Administration (FDA). All Class III devices must go through a rigorous premarket approval (PMA) process before being distributed to the public. After approval, the manufacturer must fully comply with the PMA's specifications and may not make any changes to the product or manufacturing process without submitting a supplemental PMA application to the FDA.

Mr. Sharp had an ICD implanted in his chest in 2004. His ICD consisted of a Fortify pulse generator and a Riata lead.[3] St. Jude Medical manufactured both parts of his ICD.

On August 23, 2015 between 6:45 and 7:00 a.m., Mr. Sharp suffered a cardiac arrest while driving. His ICD failed to deliver an appropriate shock to his heart to correct the arrhythmia. Mr. Sharp was pronounced dead soon after.

Mr. Sharp's doctors returned his ICD to St. Jude Medical for inspection and testing. St. Jude Medical's inspection revealed that the device had delivered high voltage therapy on August 23, 2015 at 6:56 a.m. However, the therapy was ineffective in reducing the arrhythmia because of damage to the device. Four subsequent attempts to deliver therapy were aborted due to detection of possible circuit damage. As a result, Mr. Sharp's ICD did not deliver the electrical shock his heart needed to keep him alive.

In her complaint, Ms. Sharp alleged that St. Jude Medical's manufacturing process violated federal regulations and failed to "adhere to the commitments made to the FDA in the PMA and supplemental PMA." St. Jude Medical's failure to manufacture in line with these requirements resulted in the "production of

[3] Mr. Sharp initially had his ICD implanted in October of 2004. In September of 2011, Mr. Sharp had an operation to replace his then-existing generator with a St. Jude Fortify DR generator. The Riata lead remained intact.

defective Riata leads," like Mr. Sharp's, that "render[ed] the device unreasonably dangerous for its intended use."

For example, Ms. Sharp alleged that St. Jude Medical's approved PMA required consistent insulation diameters.[4] Yet the products were manufactured with inconsistent insulation diameters—leaving some products with too much and others with too little insulation. This inconsistency increased the risk of abrasion and externalization of the wires.

Ms. Sharp alleged that externalization can cause a lead to short circuit and prevent the device from delivering life-saving treatment. Abrasion is also associated with an inability of the ICD to deliver high voltage therapy. Despite five attempts to deliver high voltage therapy, Mr. Sharp's device failed to successfully do so.

Ms. Sharp also alleged that St. Jude Medical violated Current Good Manufacturing Practices and Quality System Regulations, 21 C.F.R. § 820 *et seq.*,

[4] The dissent asserts that Ms. Sharp's PMA claims suffer from a "timing issue." We disagree. While Ms. Sharp's complaint does discuss certain PMA amendments that St. Jude Medical applied for beginning in 2005—which necessarily cannot govern Mr. Sharp's ICD that was implanted in 2004—not all discussions of the PMA violations specifically relate to these post-2005 PMAs. In fact, the complaint also alleges that St. Jude Medical applied for 14 supplements to the original PMA that were approved between 1996 and 2002, and additional applications for PMA supplements that were approved "[o]ver the next several years."

The complaint alleges defects like "inconsistent insulation diameters" that are "required by the PMA. . . to be consistent." There is no indication that the PMA discussed there was imposed only after 2004. Reasonable inferences can be made from the complaint that there were PMA insulation requirements based on the original PMA or the pre-2005 supplements. At this stage, we must make all reasonable inferences in favor of Ms. Sharp. Accordingly, she has plausibly alleged a PMA violation that affected Mr. Sharp's device.

in addition to the device-specific manufacturing parameters in the PMAs. She pointed to a 2009 FDA inspection of St. Jude Medical's manufacturing facility as evidence. After the inspection, the FDA issued a Form 483 report which documents conditions that may constitute violations of the Food and Drug Cosmetic Act and the Medical Devices Act. The 483 report issued for Defendants identified numerous potential violations that could affect the manufacturing process and lead to defective products.[5]

Additionally, Ms. Sharp identified a September 2011 FDA recall of Riata leads—because of failures associated with lead insulation abrasion—as circumstantial evidence of a defect under Georgia law. *See Miller v. Ford Motor Co.*, 653 S.E.2d 82, 84 (Ga. Ct. App. 2007) ("A product recall can serve as circumstantial evidence of an original defect … when there is first introduced some independent proof that the particular product in question suffered from the same defect." (internal quotation mark omitted)). Ms. Sharp argues that the postmortem inspection of Mr. Sharp's ICD shows that his particular device suffered from this same insulation abrasion defect.

[5] The dissent notes that the violations in the Form 483 report seem to allege design defects, not manufacturing defects. However, there is no reason that the report cannot be relevant to both types of claims. For example, plaintiffs alleged that "Defendants failed to define procedures for implementing corrective and preventative actions." This could support a claim that the design was unsafe and can also support a claim that because of those failures, nonconforming products were produced.

B. Georgia Law

Georgia's statutes provide for strict liability for defective products. A manufacturer of personal property sold as new is liable in tort to "any natural person who may use, consume, or reasonably be affected by the property" and suffers an injury to his person or property "because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained." O.C.G.A. § 51–1–11(b)(1).

Accordingly, to state a claim for strict liability the plaintiff must show that "(1) the defendant was the manufacturer of the product; (2) the product, when sold, was not merchantable and reasonably suited to the use intended, and (3) the product's defective condition proximately caused plaintiffs injury." *Brazil v. Janssen Rsch. & Dev. LLC*, 196 F. Supp. 3d 1351, 1357 (N.D. Ga. 2016); *see also Chicago Hardware & Fixture Co. v. Letterman*, 510 S.E.2d 875, 877 (Ga. Ct. App. 1999).

Under Georgia law, "[t]here are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects." *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 672 (Ga. 1994). To allege a manufacturing defect, a plaintiff must "allege the existence of a specific manufacturing defect that proximately caused the harm." *Brazil*, 196 F. Supp. 3d at 1358. "Thus, by

definition, a manufacturing defect will always be identifiable as a deviation from some objective standard or a departure from the manufacturer's specifications established for the creation of the product." *Id.* At the motion to dismiss stage, a plaintiff "need only allege [ ] a deviation and that the deviation was the proximate cause of the injury." *Morgan v. Dick's Sporting Goods, Inc.*, 359 F. Supp. 3d 1283, 1292 (N.D. Ga. 2019).

Georgia also recognizes negligence claims in relation to manufacturing defects. *See O'Shea v. Zimmer Biomet Holdings, Inc.*, 342 F. Supp. 3d 1354, 1358 (N.D. Ga. 2018). Under Georgia law, a plaintiff asserting a negligence claim must prove: (1) a legal duty to conform to a standard of conduct for the protection of others against an unreasonable risk of harm; (2) breach of that standard; (3) causation; and, (4) some loss or damage as a result of the alleged breach of the legal duty. *See Henderson v. Sun Pharms. Indus., Ltd.*, 809 F. Supp. 2d 1373, 1380 (N.D. Ga. 2011). "[A] manufacturer has a duty to exercise reasonable care in manufacturing its products so as to make products that are reasonably safe for intended or foreseeable uses." *Morgan*, 359 F. Supp. 3d at 1289 (citing *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999)).

C. Analysis

Here, Ms. Sharp has alleged a strict liability claim. She alleged (1) that St. Jude Medical manufactured her husband's ICD, (2) that the ICD was defective,

and (3) that those defects caused Mr. Sharp's death. Specifically, Ms. Sharp says that Defendants manufactured Riata leads that were not consistent with the FDA-approved PMA specifications mentioned above. These types of defects increase the risk of abrasion, which can cause short circuiting and an inability to deliver therapy—making the device not suitable for its reasonably intended use.

St. Jude Medical's postmortem inspection of Mr. Sharp's device revealed that circuit damage prevented it from delivering the necessary charges. The FDA recall of Riata leads and the 483 report, despite occurring after Mr. Sharp's lead was manufactured, allow for a plausible inference that his particular device suffered from these defects. Because the existence of a defect can be shown through circumstantial evidence alone, taking all of the allegations together, Ms. Sharp has alleged enough at this stage. *See Firestone Tire & Rubber Co. v. King*, 244 S.E.2d 905, 909 (Ga. Ct. App. 1978). Finally, Ms. Sharp alleged that the defect prevented Mr. Sharp's device from administering therapy and caused his death.

Ms. Sharp also alleged a negligence claim. Relying on the same facts, Ms. Sharp asserted that St. Jude Medical has a duty to exercise reasonable care in manufacturing ICDs to make them reasonably safe for their intended use. That duty includes strictly adhering to the protocols contained in the PMA and applicable federal regulations. St. Jude Medical breached their duty by failing to adhere to the requirements and PMAs. Ms. Sharp alleged that Defendants knew or

should have known that failure to strictly adhere to the requirements was likely to result in the production of a device with a latent defect. As a direct and proximate result of the manufacturing defect, Mr. Sharp died.

Similar allegations have been found sufficient to state claims for negligence and strict liability manufacturing defects in Georgia. *See e.g., Williams v. St. Jude Med., S.C., Inc.*, No. 16–CV–04437, slip op. at 2–3 (N.D. Ga. Oct. 19, 2017) (failing to dismiss these claims when plaintiff alleged that: an ICD was defectively manufactured because it deviated from the manufacturing standards, the defect existed at the time the product left defendant's control, the defect was the result of defendant's negligence, and the defect caused decedent's death).

III.

Ms. Sharp pleaded sufficient facts to allow this court to reasonably infer that St. Jude Medical's violations of federal regulations caused Mr. Sharp's device to fail. Accordingly, she sufficiently stated both strict liability and negligence manufacturing defect claims under Georgia law. Because the allegations in Ms. Sharp's complaint are sufficient to plausibly allege these claims, we reverse the district court's dismissal of both claims and remand for further proceedings consistent with this opinion.

REVERSED and **REMANDED.**

NEWSOM, Circuit Judge, concurring in part and dissenting in part:

I see part of this appeal differently than my colleagues do.[1] Although I have little doubt that something was amiss with Riata leads in general, I don't think that Ms. Sharp's complaint sufficiently alleged manufacturing-defect claims regarding this lead in particular. I write separately (and briefly) to explain why.

I

A

Having no quibble with the majority's recitation of the facts and procedural history, I'll skip straight to the point of divergence: whether Ms. Sharp sufficiently alleged claims for a manufacturing defect. I don't think she did.

First, a word on the taxonomy of product-defects claims under Georgia law. In Georgia, "[t]here are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects." *Banks v. ICI Americas*,

[1] A brief word on what I take to be common ground. In addition to her arguments about her manufacturing-defect claims, Ms. Sharp's briefing before us includes a few references to, and one argument about, her negligence-per-se claim. But Sharp's lone argument about her negligence-per-se claim challenges only the district court's determination that the claim was preempted by federal law. By failing to address the district court's antecedent determination that she failed to state a negligence-per-se claim as a matter of state law, Sharp "abandoned any challenge of that ground, and it follows that the judgment [in that respect] is due to be affirmed." *Sapuppo v. Allstate Floridian Ins. Co.*, 739 F.3d 678, 680 (11th Cir. 2014). The majority opinion discusses only Ms. Sharp's manufacturing-defect claims in its analysis, *see* Maj. Op. at 10–12, and I understand that to mean that it also considers any issue regarding Sharp's negligence-per-se claim to be abandoned. I concur in that much of the majority's decision, and I take the majority's reversal and remand to refer only the portion of the judgment that Sharp effectively challenged on appeal—that which concerned her manufacturing-defect claims regarding the Riata lead.

Inc., 450 S.E.2d 671, 672 (Ga. 1994); *see also* Ga. Code. Ann. § 51-1-11. A manufacturing-defect claim involves a product that falls short of "a built-in objective standard or norm of proper manufacture or design"—in short, it pertains to a particular product that came off the assembly line in bad shape. *Banks*, 450 S.E.2d at 673 n.2 (quotation marks and emphasis omitted). In contrast, "a design defect claim posits that there is a problem with the entire product line[.]" *In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010). Another piece of the background: manufacturing-defect claims can be premised on theories of strict liability or negligence. *See Boswell v. OHD Corp.*, 664 S.E.2d 262, 263 (Ga. Ct. App. 2008). Both the strict-liability- and negligence-based species of the manufacturing-defect genus require two things. A plaintiff must allege both "a defect in the product" and "a causal connection between the alleged . . . manufacturing defect and [the plaintiff's] injury." *Id.*[2]

With that in mind, I'll turn to the sources that Ms. Sharp relied on in arguing that she sufficiently alleged manufacturing-defect claims in her late husband's Riata lead. Start with the FDA's 2011 recall of Riata leads. I don't think that

[2] Because these two requirements are common to both kinds of manufacturing-defect claims at issue here, I address them jointly. And, because I would conclude that Sharp's complaint failed to state a manufacturing-defect claim of either kind, I have nothing to say about preemption. *Cf.* Maj. Op. at 4 n.2.

source supports a *manufacturing*-defect claim—of either kind—because the problems that led to the recall seem to have been caused by a *design* defect. The FDA's Recall Notice listed the "FDA Determined Cause" of the recall as "Device Design." In Sharp's operative complaint, she discusses the recall at some length and mentions both design and manufacturing defects in relation to the recall. But allegations that might support a claim of one kind won't necessarily support the other. Sharp may be right to say that her complaint "clearly alleges Mr. Sharp's leads had the same defect identified in the recalled leads," and that under Georgia law, the recall is, by itself, sufficient to indicate *some defect* in the product. *See Miller v. Ford Motor Co.*, 653 S.E.2d 82, 84 (Ct. App. Ga. 2007). But, insofar as the defect that spawned the recall was a design defect, that allegation doesn't support manufacturing-defect claims.

Next, Sharp's allegations of a manufacturing defect assert various violations of certain federal requirements. Broadly speaking, I think those requirements can be put in two classes: (1) those related to the PMAs issued for the Riata lead, and subsequent supplements to those PMAs; and (2) CGMP regulations.

As I see it, the PMA-related allegations suffer from a timing issue. Specifically, Sharp's allegations concern failures to live up to standards that the FDA set *after* Mr. Sharp's lead had been implanted. For example, the complaint said that during the time from "2005-2010 St. Jude applied for at least 27

manufacturing or process changes to the Riata leads" that the FDA approved, but that "St. Jude failed to manufacture the Riata leads in a manner consistent with these approved changes . . . ." And then it details various alleged violations of those standards. On appeal, those alleged violations formed the centerpiece of Ms. Sharp's argument, and each details how a particular deviation from a particular PMA requirement led to a problem with the insulation in Riata leads. In a vacuum, it's clear enough that alleged violations of those standards support a manufacturing-defect claim. But not these claims—that's because those allegations involve standards set in 2005 (at the earliest), and Mr. Sharp's lead was implanted in his chest in 2004, which means it was manufactured in 2004 (at the latest). I don't see how standards from 2005 and thereafter can provide the standard by which one judges such a lead.

With respect to the allegations involving CGMPs, the problem isn't so much one of timing as it is of causation. For a bit of context, CGMPs "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a). And Sharp's complaint points out that the FDA issued a Form 483 letter in 2009 detailing potential violations of these regulations. But I don't understand how these alleged violations relate to a manufacturing defect. For instance, the complaint alleges that "[St. Jude] failed to

perform design reviews at appropriate times" and that "team meeting minutes were not maintained as required." It's not self-evident to me what those failures have to do with manufacturing-defect claims, and Sharp doesn't do much to help us connect the dots. The same is true for an alleged failure to "resolve discrepancies noted at the completion of design verification." So too with respect to the allegations about risk analysis and reporting requirements—those might have supported other claims Sharp made (like failure-to-warn claims), but I don't see how they relate to Sharp's manufacturing-defect claims.

* * *

In sum: I think that (1) the FDA's recall points to a different kind of defect, (2) the PMA and PMA supplements that Sharp connects to a manufacturing-defect postdate the making of this particular device, and (3) Sharp didn't link the alleged violations of CGMPs to a manufacturing-defect. As a result, I don't think the complaint here stated a claim for a manufacturing defect and I would affirm the district court's judgment on that basis. Because my colleagues conclude otherwise, I must respectfully dissent from that much of the majority's judgment.