[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 16-11646

D.C. Docket No. 0:15-cv-61210-BB

JOSEPH MINK,

Plaintiff-Appellant,

versus

SMITH & NEPHEW, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Florida

(June 26, 2017)

Before WILLIAM PRYOR, MARTIN, and BOGGS,[*] Circuit Judges.

MARTIN, Circuit Judge:

[*] Honorable Danny J. Boggs, United States Circuit Judge for the Sixth Circuit, sitting by designation.

Joseph Mink appeals the District Court's dismissal of his case against Smith & Nephew, Inc. ("S&N"), which brought four claims under Florida law. Mr. Mink's negligence, product liability, breach of contract, and misrepresentation claims stem from his decision to get S&N's metal-on-metal hip replacement system and the injuries he says it caused him. This system is a medical device regulated by the Food and Drug Administration ("FDA"). The District Court dismissed Mr. Mink's claims after finding they were not viable under Florida law and, in any event, were expressly and impliedly preempted by federal law. After careful consideration, and with the benefit of oral argument, we affirm the District Court's dismissal of Mr. Mink's negligence claim to the extent it relies on an improper training or failure to warn theory of liability. We also affirm the dismissal of Mr. Mink's breach of contract claim. We reverse the District Court's dismissal of Mr. Mink's negligence claim and strict product liability claims premised on manufacturing defect, as well as his misrepresentation claim.

I. BACKGROUND

A. THE FACTS

S&N develops and manufactures joint replacement systems. One of its systems is the Birmingham Hip Resurfacing ("BHR") System, which is a metal-on-metal hip replacement system. As a Class III medical device, the BHR System requires premarket approval from the FDA before it can be made commercially

available. The FDA gave this approval in May 2006, but set conditions. One condition was that S&N conduct a post-approval study to be sure of the device's safety and effectiveness over time. This study included assessments of renal function and monitoring of metal ion levels in a patient's blood.

Mr. Mink's doctor told him he needed a hip replacement. His doctor scheduled the surgery, planning to use a hip replacement system other than S&N's. However, before his surgery, Mr. Mink saw an advertisement for S&N's BHR system and contacted S&N about it. S&N referred Mr. Mink to Dr. Jason Weisstein, who was a local orthopedic surgeon and served as an S&N representative. Dr. Weisstein told Mr. Mink he could get the BHR System as a part of S&N's 10-year post-approval study. He also told Mr. Mink that as a study participant, Mr. Mink would be regularly monitored and tested for 10 years at no cost. Mr. Mink liked the sound of that. He agreed to use the BHR System as his hip replacement system and signed the consent form to enter the study. He believed he would get better monitoring and medical attention from S&N than he would get from a competitor's product that came with no study or related free benefits.

On June 6, 2011, Mr. Mink had the hip replacement surgery and got the BHR System. About seven weeks later, on August 1, 2011, Dr. Weisstein informed Mr. Mink that he was moving away and could no longer see Mr. Mink

for the BHR study. But Dr. Weisstein assured Mr. Mink that he would find another local doctor so that Mr. Mink could continue to participate in the BHR study and receive its benefits. On August 18, 2011, Dr. Weisstein told Mr. Mink that S&N had arranged for his continued participation in the study with Dr. Gregory Martin. So Mr. Mink visited Dr. Martin. To his surprise, Dr. Martin had never heard about Mr. Mink or his participation in the BHR study. To add insult to Mr. Mink's injury, he also got a bill for his visit to Dr. Martin. On May 14, 2012, S&N told Mr. Mink it could not find a clinical site for him to continue participating in the BHR study. S&N terminated Mr. Mink from the study and told him so.

As time passed, Mr. Mink experienced higher-than-normal chromium and cobalt levels in his blood. In light of this, he had the metal-ion levels in his blood closely monitored even after he was terminated from the study—only now at his own expense. Unfortunately, Mr. Mink's problems with the BHR System only got worse. He began to experience eye problems, and his left inguinal lymph node, near the site of his hip replacement, became so enlarged it had to be surgically removed. Mr. Mink's blood toxicity from the chromium and cobalt leaching from the BHR System continued to worsen as well. Eventually, on November 17, 2014, Mr. Mink had to have the BHR System removed in what is called a "revision" surgery.

B. PROCEDURAL HISTORY

Mr. Mink brought four claims under Florida law against S&N. They are claims for (1) negligence; (2) strict product liability; (3) breach of contract; and (4) misrepresentation. His negligence claim is, in turn, premised on three possible theories: (1) a defect in the manufacturing process; (2) inadequate or improper training; and (3) failure to report adverse events. His strict product liability claim is also based on a manufacturing defect theory. The strict product liability claim alleged that S&N violated the FDA-required manufacturing specifications in the BHR System he got. His breach of contract claim alleges that S&N breached its agreement with him about the BHR study. And his misrepresentation claim is based on misrepresentations that Mr. Mink says S&N made about the free medical care he would receive as well as misrepresentations about the product having been proven safe in England. He says these misrepresentations induced him to get S&N's BHR system instead of a competitor's hip replacement product.

The District Court granted S&N's motion to dismiss. S&N argued that all four of Mr. Mink's claims failed to state a claim upon which relief could be granted because they were barred under Florida state law; expressly preempted by federal law; and impliedly preempted by federal law. The District Court found all claims due to be dismissed because: (1) the negligence claim was barred under Florida law, and alternatively, impliedly preempted by federal law; (2) the strict

product liability claim was impliedly preempted by federal law; (3) the breach of contract claim failed under Florida law, and alternatively, was expressly preempted by federal law; and (4) the misrepresentation claim "succumb[ed] to the same legal theories which force[d] the dismissal of the previously-discussed claims." All of Mr. Mink's claims were dismissed with prejudice. This appeal followed.

II. STANDARD OF REVIEW

We review de novo the District Court's dismissal of a complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). Hill v. White, 321 F.3d 1334, 1335 (11th Cir. 2003) (per curiam). A plaintiff's allegations are accepted as true and we construe his complaint in the light most favorable to him. Id. We also 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). We may affirm the District Court on any ground supported by the record, regardless of whether the District Court relied on it. See Krutzig v. Pulte Home Corp., 602 F.3d 1231, 1234 (11th Cir. 2010).

III. FEDERAL PREEMPTION LAW

A. THE MEDICAL DEVICE AMENDMENTS

The Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq., were enacted to amend the FDA's enabling statute, the Food, Drug, and Cosmetic Act, id. § 301 et seq. The Medical Device Amendments gave the FDA regulatory

authority over medical devices for human use. See § 360c et seq. Under that authority, the FDA classifies medical devices into three categories, depending on the level of risk presented. See Riegel v. Medtronic, Inc., 552 U.S. 312, 316–17, 128 S. Ct. 999, 1003 (2008). All metal-on-metal hip replacements are considered "Class III" medical devices, which is the highest category of risk. See id.; 21 U.S.C. § 360c(a)(1); 21 C.F.R. § 888. Any company wanting to sell a metal-on-metal hip replacement system is required to undergo the FDA's "premarket approval" process. 21 C.F.R. § 814.1.

Premarket approval is a rigorous process of federal review that evaluates a medical device's safety and effectiveness. See Riegel, 552 U.S. at 317–20, 128 S. Ct. at 1004–05 (describing this process). This process takes, on average, about 1,200 hours of review by the FDA. Id. at 318. For each device, the FDA compiles a large amount of data and carefully weighs the risks and benefits. See id. Even once approved, the FDA regularly attaches specific conditions to a device. See id. at 319; 21 U.S.C. § 360j(e)(1). And after the FDA approves a device, the manufacturer may not make any change to the device's specifications, or anything else that might affect its safety and effectiveness, unless it submits a supplemental application to the FDA. 21 U.S.C. § 360e(d)(5)(A)(i). The FDA must be informed of changes to the manufacturing process. Id. The manufacturer must report

information to the FDA, including new studies about the device and any adverse events. Id. § 360i; 21 C.F.R. §§ 803.50(a), 814.84(b)(2).

The Medical Device Amendments contain, among other things, two provisions that are central to this appeal. They are 21 U.S.C. § 360k(a), the "express preemption" provision, and 21 U.S.C. § 337(a), the "implied preemption" provision. S&N argues that these two provisions preempt all of Mr. Mink's state law claims.

B. EXPRESS PREEMPTION

Section 360k(a) applies to Class III medical devices and says:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). This provision does not allow a state to impose a requirement on a Class III medical device that is "different from, or in addition to" any federal requirement on the device. See id. Any state requirement that does this is expressly preempted by federal law.

The Supreme Court has considered Section § 360k(a) in some depth. See Riegel, 552 U.S. 312, 128 S. Ct. 999; Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Ct. 2240 (1996). In Lohr, the Court made clear that § 360k(a) did not preempt all

state-law claims. 518 U.S. at 495, 116 S. Ct. at 2255. The Court explained that state common law claims could still be pursued by plaintiffs if the claims were based on the violation of federal law:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Id. at 495, 116 S. Ct. at 2255. Applying this reasoning, the Supreme Court decided in Lohr that the plaintiff's state common law claims based on negligent design and defective manufacturing or labelling were not preempted to the extent their claims paralleled federal requirements. See id. at 492–503, 116 S. Ct. at 2253–59.[1]

In Riegel, the Supreme Court held the plaintiff's New York state-law claims for strict liability, breach of implied warranty, and negligence were expressly

[1] It is worth mentioning that the device in Lohr went through the § 510(k) premarket notification process for devices "substantially equivalent" to a device already on the market instead of the more rigorous premarket approval process here. Lohr, 518 U.S. at 478–80, 116 S. Ct. at 2247–28. But the Court's explanation about parallel claims applies in the premarket approval context as well. See id. at 494, 116 S. Ct. at 2254–55; Riegel, 552 U.S. at 330, 128 S. Ct. at 1011.

preempted because they imposed requirements that went beyond the federal regulations on the medical device at issue there. 552 U.S. at 320, 330, 128 S. Ct. at 1006, 1011. But the Court was careful to say that duties imposed by state law are preempted only to the narrow extent that they add different or extra requirements to the safety and effectiveness of the medical device beyond those required by the federal scheme. See id. at 330, 128 S. Ct. at 1011. "Parallel" state duties survive so long as they claim a violation of state tort law that aligns with a federal requirement. See id. In contrast, a claim that a device "violated state tort law notwithstanding compliance with the relevant federal requirements" would clearly be preempted. Id.

Our Court examined Riegel in Wolicki-Gables v. Arrow International, Inc., 634 F.3d 1296 (11th Cir. 2011). We said that state law claims could survive § 360k if the state requirements were "genuinely equivalent" to the federal ones. Id. at 1300 (quotation omitted). We adopted a two-prong test to determine if a state-law claim is expressly preempted:

> First, a court must determine whether the Federal Government has established requirements applicable to the device. If so, the court must then determine whether the plaintiff's common-law claims are based upon state law requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to the safety and effectiveness.

Id. at 1301 (quotations omitted and alterations adopted). The Wolicki-Gables panel said that any device that goes through premarket approval will necessarily

have federally established requirements. See id. The panel concluded that the claims asserted by the plaintiff in Wolicki-Gables were expressly precluded because nothing "specifically stated in the initial pleadings" what parallel federal requirements had been violated. Id.

C. IMPLIED PREEMPTION

Section 337(a) governs implied preemption. It requires that, with exceptions not relevant here, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a) (emphasis added). This is sometimes called the "no-private-right-of-action" clause.

The Supreme Court examined this statute in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S. Ct. 1012 (2001). In Buckman, the plaintiffs brought state-law fraud claims asserting fraudulent representations made to the FDA by the manufacturer of an orthopedic bone screw, a Class III medical device. Id. at 346–47, 121 S. Ct. at 1016. The Supreme Court held that these state law claims were impliedly preempted because "the plaintiffs' state-law fraud-on-the-FDA claims conflict with . . . federal law." Id. at 348, 121 S. Ct. at 1017. The Court reasoned that the claims made in Buckman asserted the power given to the FDA to punish and deter fraud against itself, and that it was the FDA that had the

authority to balance the statutory objectives at issue—not a private plaintiff. See id.

But the Court made the distinction between the "fraud-on-the-agency claims" in Buckman and "traditional state tort law [that] predated the federal enactments in question[]." Id. at 353, 121 S. Ct. at 1020. Thus, the Supreme Court told us that traditional state-law tort claims survive implied preemption so long as they don't seek to privately enforce a duty owed to the FDA. See id.

D. EXPRESS AND IMPLIED PREEMPTION APPLIED

Our Court has no published opinion examining how these two preemption provisions work together, as applied to a Class III medical device that has gone through the FDA's premarket approval process. To avoid having his claims preempted, a plaintiff must carefully plead a claim that implicates the safety or effectiveness of a federally-regulated medical device. Express preemption will bar state-law claims that impose on the medical device a requirement different from or additional to federal requirements. See Riegel, 552 U.S. at 321–22, 128 S. Ct. at 1006; Wolicki-Gables, 634 F.3d at 1301–02. And implied preemption prohibits state-law claims that seek to privately enforce duties owed to the FDA. See Buckman, 531 U.S. at 348, 121 S. Ct. at 1017.

These two types of preemption, operating in tandem, have created what some federal courts have described as a "narrow gap" for pleadings. In re

Medtronic, Inc., 623 F.3d 1200, 1204 (8th Cir. 2010) (quotation omitted). To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption). Id. Putting these ideas into practice, the Seventh Circuit says a plaintiff may proceed on her claim so long as she claims the "breach of a well-recognized duty owed to her under state law" and so "long as she can show that she was harmed by a violation of applicable federal law." Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010).

IV. MR. MINK'S CLAIMS

As we've said, Mr. Mink brought four Florida state-law claims. We will evaluate whether each claim was properly pled under Florida law. Then we'll examine whether federal law preempts the claim, either by express or implied preemption. Because preemption is a principle derived from the Supremacy Clause, U.S. Const. Art. VI, cl. 2, we must first analyze whether each claim can stand under state law, and only then decide the preemption questions where necessary. See Slack v. McDaniel, 529 U.S. 473, 485, 120 S. Ct. 1595, 1604 (2000) (explaining courts should "not pass upon a constitutional question although properly presented by the record, if there is also present some other ground upon which the case may be disposed of" (quotation omitted)).

We will examine each of Mr. Mink's four state-law claims. But first, it's worth addressing the recent Florida decision in Wolicki-Gables v. Doctors Same Day Surgery Center, Ltd., ___ So. 3d ___, 2017 WL 603316 (Fla. 2d DCA Feb. 15, 2017) (Wolicki-Gables II).[2] S&N urges us to defer to this decision so as to hold that Florida law does not recognize a parallel claim under the Medical Device Amendments. This interpretation would mean that none of Mr. Mink's claims can proceed. We decline this invitation because the Wolicki-Gables II ruling was based on a misapprehension of what federal law requires. Because Florida courts are not the source of federal law, their interpretation of federal law does not bind us. The Wolicki-Gables II court said, mistakenly, that as a general matter, "[c]ommon law damage claims are inadequate to escape federal preemption," and only then determined that Florida law does not create any other private right of action based on the federal statute. Id. at *5–6. But as we set out above, common law causes of action may avoid federal preemption so long as there is a state duty that is owed to the plaintiff and the common-law claim imposes only requirements that parallel the federal requirements. The court in Wolicki-Gables II ruled that there was no implied private right of action created by the federal statute or any other source of Florida law. The Wolicki-Gables II court did not overturn existing

[2] Both our Court and the Florida Second District Court of Appeal have had a Wolicki-Gables case. In our discussion, we have undertaken to be clear about whether we are referring to the state or the federal case.

Florida law about negligence claims that relate to a statutory violation. See Fla. Dep't of Corr. v. Abril, 969 So. 2d 201, 205 (Fla. 2007) (per curiam) ("The courts of Florida have long recognized that the violation of a statute may be utilized as evidence of negligence."); id. (recognizing a "statute, ordinance, or administrative rule or regulation" all could be "prima facie evidence of negligence" (quotation omitted)).

The position S&N asks us to adopt would mean that, as S&N said at oral argument, no Florida state law claim could ever be brought against it, no matter how it is pled. But the Supreme Court has already told us this is not what Congress did when it enacted the Medical Device Amendments. See Lohr, 518 U.S. at 487, 116 S. Ct. at 2251 (plurality opinion); id. at 494–95, 116 S. Ct. at 2254–55 (majority opinion). The Supreme Court made clear that the plain text of the Medical Device Amendments was not intended to "have the perverse effect of granting complete immunity from [tort] liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order to provide for the safety and effectiveness of medical devices intended for human use." Id. at 487, 116 S. Ct. at 2251 (plurality opinion) (quotation omitted). S&N's position seeks immunity beyond what the Medical Device Amendments provide. Manufacturers of Class III medical devices subjected to premarket approval are protected from civil liability under § 360k to the extent that they comply with federal law. But

where the plaintiff can prove he was hurt by a manufacturer's breach of a common-law duty owed to him and that duty is parallel to the requirements of federal law, there is no preemption. See id.; Bausch, 630 F.3d at 549–50.

Mr. Mink's claims are Florida common law causes of action, not private rights of action enforcing the violation of a statute. Whether these common law causes of action were properly alleged under Florida law, or impose requirements that raise preemption issues, are questions we address now.

A. NEGLIGENCE

Mr. Mink bases his negligence claim on three possible theories of liability: (1) manufacturing defect; (2) inadequate or improper training; and (3) failure to report. His complaint alleges negligence by S&N on all three of these theories, but expressly limits his claims to those that "are parallel to and not different from or in addition to the requirements of federal law." Mr. Mink says S&N violated a number of the FDA's premarket approval requirements for the BHR System as well as a number of federal regulations. He argues that these federal violations establish a prima facie case of Florida common law negligence, and reiterates that he is pleading this Florida claim only to the extent that it parallels federal law.

Of Mr. Mink's three theories of liability for his negligence claim, only the manufacturing defect theory may proceed. The improper training theory is barred by Florida law. And the failure to report theory is impliedly preempted.

1. Florida State Law

Mr. Mink properly pled his manufacturing defect theory under Florida law. Mr. Mink says his BHR System was defective because "a properly manufactured BHR system would not cause immediate and toxic levels of chromium and cobalt in [his] blood from the date of surgery." Florida law recognizes common law negligence claims based on a manufacturing defect theory of liability. See Ford Motor Co. v. Evancho, 327 So. 2d 201, 202 (Fla. 1976) (holding that manufacturers may be liable for a manufacturing defect that causes or enhances injury).

So too is Mr. Mink's "failure to report adverse events" theory properly pled under Florida law. Although Mr. Mink describes this claim using various terms, Florida law recognizes this theory as "negligent failure to warn." Mr. Mink alleges that S&N violated its common law duties to warn generally about the dangers the BHR System posed, and that S&N had a post-sale duty to warn because it was required to report adverse events to the FDA. Florida law recognizes the common law duty of failure to warn as a basis for a negligence claim. See Aubin v. Union Carbide Corp., 177 So. 3d 489, 514 (Fla. 2015); High v. Westinghouse Elec. Corp., 610 So. 2d 1259, 1262–63 (Fla. 1992) (recognizing manufactures may be negligent for failing to warn entities that sell their product).

On the other hand, Florida law does not allow the improper training theory to proceed. Mr. Mink says S&N had a duty to correctly train the doctor on how to implant the BHR System in him. But under Florida law, the learned-intermediary doctrine bars this theory of negligence. See Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989) ("[T]he prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend [something] to meet the patient's needs."); see also Rounds v. Genzyme Corp., 440 F. App'x 753, 755–56 (11th Cir. 2011) (per curiam) (unpublished) (holding the learned-intermediary doctrine barred a failure-to-train claim under Florida law). S&N's duty in this regard, if any, was to the physician, not Mr. Mink. See id. We therefore affirm the District Court's dismissal of Mr. Mink's negligence claim to the extent it was premised on an improper training theory.

2. Implied Preemption

Mr. Mink's manufacturing defect theory is not impliedly preempted by federal law, but his failure to report theory is. As set out above, in Buckman, the Supreme Court held that "state-law fraud-on-the-FDA claims" conflicted with, and were therefore impliedly preempted, by federal law. 531 U.S. at 348, 121 S. Ct. at 1017. But the Court said traditional state tort law causes of action that predated the federal enactments, and did not implicate a duty owed to the FDA, are generally

not impliedly preempted. See id. at 353, 121 S. Ct. at 1020; see also id. at 354, 121 S. Ct. at 1020 (Stevens, J., concurring).

Applying Buckman, Mr. Mink's failure to report theory is impliedly preempted. Mr. Mink's theory relies on his allegation that S&N "failed to adequately investigate adverse events and complaints and failed to properly report these issues to the FDA." Because this theory of liability is based on a duty to file a report with the FDA, it is very much like the "fraud-on-the FDA" claim the Supreme Court held was impliedly preempted in Buckman. In both cases, a plaintiff alleged a manufacturer failed to tell the FDA those things required by federal law. And here, like Buckman, we conclude that federal law preempts these claims insofar as S&N's duty is owed to the FDA and Mr. Mink's theory of liability is not one that state tort law has traditionally occupied. We therefore affirm the District Court's dismissal of Mr. Mink's negligence claim to the extent it was premised on a "failure to report" theory.

In contrast, Mr. Mink's manufacturing defect theory falls into the category of traditional state tort law that is not impliedly preempted. The duty of a manufacturer to use due care in manufacturing a medical device predates the Medical Device Amendments, and is a duty that S&N owes Mr. Mink (as opposed to the FDA). This theory of liability is therefore not impliedly preempted by federal law.

3. Express Preemption

Neither is Mr. Mink's manufacturing defect theory expressly preempted by federal law. As the Supreme Court recognized in Lohr: "Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495, 116 S. Ct. at 2255. Mr. Mink alleges that S&N violated the Florida common law duty to use due care in manufacturing a medical device. This duty is parallel to the federal requirement that the BHR System be manufactured according to the approved specifications for the medical device. Said another way, Mr. Mink alleges that S&N's violation of a federal requirement also caused the violation of a state-law duty.

Florida law allows the violation of a federal requirement to serve as prima facie evidence of negligence. See Abril, 969 So. 2d at 205. So Florida law does not impose any different or additional requirement on the device. See 21 U.S.C. § 360k(a). The holding in Riegel was limited to violations of state tort law "notwithstanding compliance with the relevant federal requirements." 552 U.S. at 330, 128 S. Ct. at 1011. Thus, as long as the state tort law claim is premised on a violation of federal law, it survives if it does not impose new requirements on the medical device. And even if there are some additional elements that must be proven under Florida law, the claim is not expressly preempted so long as the

Florida elements do not implicate any additional requirement on the device itself. See Lohr, 518 U.S. at 495, 116 S. Ct. at 2255 (holding these additional elements make the state requirements "narrower, not broader, than the federal requirement"). In sum, this claim is precisely the type the Supreme Court has told us survives express preemption. See Riegel, 552 U.S. at 330, 128 S. Ct. at 1011.

S&N argues that this Court's precedent in Wolicki-Gables forecloses Mr. Mink's claim, because it held the plaintiffs' Florida manufacturing defect claim was expressly preempted. 634 F.3d at 1301–02. But Wolicki-Gables dismissed the plaintiffs' claim because of pleading deficiencies: the plaintiffs did not carefully plead the Florida duties to the extent they paralleled federal requirements, and they did "not set forth any specific problem, or failure to comply with any FDA regulation that [could] be linked to the injury alleged." Id. (quotation omitted). In quite the contrast, Mr. Mink carefully pled his claims only to the extent the Florida state-law duties paralleled federal requirements. And he pointed to device-specific federal requirements he says S&N violated, including the premarket approval specifications for the device, see 21 C.F.R. § 814.80, as well as a number of other specific federal regulations.[3]

[3] To the extent S&N argues that some of the federal regulations cited by Mr. Mink are not sufficiently device-specific, we reject its argument. We agree with our sister circuits that there is no "sound legal basis" to distinguish these federal requirements because the plain text of § 360k refers to "any requirement." Bausch, 630 F.3d at 555; see Howard v. Sulzer Orthopedics, Inc., 382 F. App'x 436, 440–41 (6th Cir. 2010).

We thus conclude that Mr. Mink's negligence claim is not preempted by federal law to the extent that it is premised on a manufacturing defect theory in violation of federal requirements. We reverse the District Court's finding in this regard.

B. STRICT PRODUCT LIABILITY

Mr. Mink's second claim is strict product liability premised on a manufacturing defect theory. Our analysis on this claim is nearly the same as the analysis on Mr. Mink's negligence claim premised on this same theory. In both claims, Mr. Mink alleges the BHR System was not manufactured in a way that was consistent with the FDA premarket approval specifications, as required by 21 C.F.R. § 814.80. More to the point, Mr. Mink says the BHR System he got was manufactured with material that did not meet the FDA's requirements for hardness, durability, composition, and finish. He says these defects were the proximate cause of his injuries.

Florida law allows this claim because it recognizes that manufacturers may be held strictly liable for an injury to the user of its product. See West v. Caterpillar Tractor Co., 336 So. 2d 80, 86–87 (Fla. 1976). And the claim is not expressly preempted by federal law for the same reasons as the negligence claim premised on this theory. It is a state common law tort claim based on the violation of a parallel federal requirement. Neither is this claim impliedly preempted by

federal law, again for the same reasons as before: the duty enforced here is the traditional state tort duty of a manufacturer to use due care in manufacturing the medical device. No duty is owed to the FDA. We therefore reverse the District Court's dismissal of Mr. Mink's strict product liability claim.

C. BREACH OF CONTRACT

Mr. Mink alleges that Dr. Weisstein was S&N's express and implied agent.[4] Dr. Weisstein offered to sell the BHR System to him with the additional consideration that Mr. Mink would be in the BHR study (and receive its free benefits). Mr. Mink alleges he therefore had a contract with S&N.

While there appears to be a genuine question of fact about whether Mr. Mink had an oral contract with S&N, when we heard oral argument in this case, Mr. Mink's counsel told us this claim is limited solely to the written consent agreement he signed with S&N. And based on the written consent agreement, we agree with the District Court that Mr. Mink did not properly allege facts necessary to establish a breach of contract claim. Florida law requires that "[t]o state a cause of action for breach of contract, a complaint need only allege facts that establish the existence of a contract, a material breach, and resulting damages." Baron v.

[4] S&N disputes whether Dr. Weisstein was its agent. But Mr. Mink alleges that he was, and at this pre-discovery stage that's enough, because agency is a question of fact under Florida law. See S. Fla. Coastal Elec., Inc. v. Treasures on Bay II Condo. Ass'n, 89 So. 3d 264, 267 (Fla. 3d DCA 2012) ("Whether an agency relationship exists is generally a question of fact, and thus disputes regarding the material facts in support of agency will prevent summary judgment.").

Osman, 39 So. 3d 449, 451 (Fla. 5th DCA 2010) (per curiam). And to establish the existence of a contract, Mr. Mink must show that the "basic requirements of contract law" under Florida law were met, including "offer, acceptance, consideration and sufficient specification of essential terms." St. Joe Corp. v. McIver, 875 So. 2d 375, 381 (Fla. 2004).

In his complaint, Mr. Mink alleged that the consent form he signed was a "binding commitment" by S&N "in consideration for [him] agreeing to purchase the product and have the BHR system implanted." He also listed a number of medical procedures and examinations he says the consent form promised him. But even assuming the consent form was a valid contract, Mr. Mink never alleged that S&N breached any of these promises in the form. Instead he alleged only that S&N breached an "oral contract." Because Mr. Mink has conceded any claim based on an oral contract between him and S&N, and has failed to allege any breach of a written contract, we affirm the District Court's dismissal of this claim.

D. MISREPRESENTATION

In his misrepresentation claim, Mr. Mink alleges Dr. Weisstein represented to him that if he got the BHR System, he would receive 10 years of medical monitoring, testing, and examinations—all paid for by S&N. He also says Dr. Weisstein told him the BHR System had been used successfully in England since 1997 and was a better product than the alternatives on the market for someone his

age. But Mr. Mink claims S&N knew or should have known that all of these representations were false. He alleges he reasonably relied upon these misrepresentations, which induced him to get the BHR System, which in turn caused him physical injuries, economic loss, and other damages.

1. Florida Law

This claim may proceed under Florida law as a fraudulent misrepresentation claim. Florida law establishes four elements of fraudulent misrepresentation: "(1) a false statement concerning a material fact; (2) the representor's knowledge that the representation is false; (3) an intention that the representation induce another to act on it; and (4) consequent injury by the party acting in reliance on the representation." Butler v. Yusem, 44 So. 3d 102, 105 (Fla. 2010) (per curiam) (quotation omitted). Mr. Mink's allegations satisfy these requirements. He alleged that S&N made materially false representations; that S&N knew or should have known its material representations were false; that the false misrepresentations induced him to get the BHR System; and that the false representations caused his injury because he reasonably relied upon them.

2. Express Preemption

Mr. Mink's misrepresentation claim is not expressly preempted by federal law. This claim is based solely on representations made to him by S&N. The plain language of § 360k(a) prohibits state-law requirements that "relate[] to the

safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." 21 U.S.C. § 360k(a) (emphasis added); see also Riegel, 552 U.S. at 322, 128 S. Ct. at 1006 (holding § 360k can only bar "common-law claims [] based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness"). Mr. Mink's claim does not rely on any new or additional safety or effectiveness requirements for the BHR System. Rather, he says Dr. Weisstein, S&N's agent, fraudulently induced him to get the device.

S&N argues this claim does relate to the BHR System's safety and effectiveness because it would not exist but-for the FDA's required post-approval BHR study. See 21 C.F.R. § 814.82(a)(2). It says the BHR study was therefore a federal requirement, and Mr. Mink's claim imposes additional state requirements that must be preempted. This argument fails for two reasons. First, the representations S&N allegedly made to Mr. Mink do not impose any safety or effectiveness requirements on the BHR System. Second, and in any event, if these representations did impose any new requirements on the BHR System, they were undertaken by S&N, not imposed by the state of Florida. See 21 U.S.C. § 360k(a) ("[N]o State . . . may establish . . . any requirement . . . ." (emphasis added)). These boundaries for preemption comport with those the Supreme Court has set in other preemption contexts. See, e.g., Cipollone v. Liggett Grp., Inc., 505 U.S. 504,

525 & n.23, 112 S. Ct. 2608, 2622 & n.23 (1992) (plurality opinion) (holding petitioner's claim for the breach of an express warranty was not preempted under the Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(b), because it "sound[s] in contract" and therefore was not "imposed under State law" but instead "imposed by the warrantor" (quotations omitted)). Because the alleged representations were made by S&N to Mr. Mink, any additional or different requirement they imposed on the BHR System could not have been imposed by Florida. Therefore, this claim is not expressly preempted by federal law.

3. Implied Preemption

Neither is Mr. Mink's misrepresentation claim impliedly preempted by federal law. Section 337(a) can prohibit only actions to enforce FDA requirements by private parties. See 21 U.S.C. § 337(a); see also Buckman, 531 U.S. at 348, 121 S. Ct. at 1017. The misrepresentation claim here, for the same reasons explained above, is not enforcing any FDA requirement on S&N. Although this claim does have some relation to the BHR study, it seeks to remedy S&N's material false statements that were relied upon by Mr. Mink. As a result, this claim is not impliedly preempted, and we reverse its dismissal by the District Court.

IV. CONCLUSION

We affirm the District Court's dismissal of Mr. Mink's negligence claim to the extent it is premised on an improper training or failure to warn theory of liability. We also affirm the District Court's dismissal of his breach of contract claim. We reverse the District Court's dismissal of Mr. Mink's negligence claim and strict product liability claims premised on manufacturing defect, as well as his misrepresentation claim. These surviving claims are cognizable Florida common law causes of action and are not preempted by federal law. It remains to be seen if Mr. Mink can prove his allegations, but they are properly pled and not preempted.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.