IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
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Lyle W. Cayce
Clerk

No. 09-60925

JAN HUGHES,

Plaintiff-Appellant

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant-Appellee

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

Before KING, GARWOOD, and DAVIS, Circuit Judges.

W. EUGENE DAVIS, Circuit Judge.

This appeal requires us to determine the extent to which Appellant Jan Hughes's state tort claims seeking recovery for injuries allegedly caused by a medical device manufactured by Appellee Boston Scientific Corporation ("Boston Scientific") are preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 301 *et seq*., to the Federal Food, Drug, and Cosmetics Act of 1938 ("FDCA"), 52 Stat. 1040. The district court granted Boston Scientific's motion for summary judgment, holding that all of Hughes's claims are preempted. Hughes now appeals that ruling, focusing primarily on her claim that Boston Scientific failed to provide adequate warnings of dangers or risks associated with the HTA. For the following reasons, we affirm the district court's ruling with

regard to all of Hughes's claims except for her failure to warn claim to the extent that this claim is predicated on Boston Scientific's failure to comply with the applicable federal statutes and regulations. Because we conclude that this claim is not preempted, we remand that claim to the district court for further proceedings, consistent with this opinion.

I.

A.

Boston Scientific is the designer, manufacturer, marketer, and seller of the HydroThermAblator ("HTA"), a medical device designed for the treatment of menorrhagia, or excess uterine bleeding. The device works by circulating hot saline solution (194° F) through a closed cycle into and then flushing it from the uterus, causing the lining of the uterus to slough off and discharge.

The HTA was approved for entry into the market by the Food and Drug Administration ("FDA") under its rigorous premarketing approval ("PMA") process in 2001. Boston Scientific sold the HTA device on the market from 2002 to 2009.[1] The HTA was classified as a Class III medical device under the MDA, thus receiving the highest degree of FDA oversight.

Class III devices are those that either "presen[t] a potential unreasonable risk of illness or injury" or are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). As part of the PMA approval process, manufacturers of Class III devices must provide the FDA with a "reasonable assurance" that the device is both safe and effective. *Id.* § 360e(d)(2). The applicant must submit detailed information including full reports of all relevant information that is known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for

[1] Boston Scientific acquired the HTA from another company in 2002 and voluntarily recalled the device on July 31, 2009.

manufacturing and installation of the device. *Id*. § 360e(c)(1). In its review, the agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Id*. § 360c(a)(2)(C). Once a device has received PMA approval, the manufacturer cannot make changes to any feature of the device without obtaining FDA permission. *Id*. § 360e(d)(6).

After PMA approval, manufacturers of Class III devices must comply with Medical Device Reporting ("MDR") requirements. *Id*. § 360i(a)(1); 21 C.F.R. § 803.50(a). The FDA may approve marketing of the Class III device subject to additional postapproval conditions, which the FDA may include in its PMA approval order. *See* 21 U.S.C. §§ 360c-360j; 21 C.F.R. §§814.80, 814.82. If a manufacturer fails to comply with the FDA regulations or postapproval conditions, the FDA has the power to withdraw PMA approval, as well as the power to impose other remedies such as additional warnings or corrective labeling. *See* 21 U.S.C. §§ 351, 352, 360(h), 374.

B.

Hughes filed a complaint against Boston Scientific in the Circuit Court of Jones County, Mississippi, on March 26, 2008, seeking recovery for injuries she allegedly sustained from the HTA device. Hughes alleges that on October 25, 2006, her treating physician, Dr. Weber, performed the ablation procedure on her using the HTA device. During the procedure, hot liquid leaked from the device, at which point the device's alarm sounded and shut down, as it is designed to do. The leak caused a three-inch by two-inch burn on Hughes's outer perineal body and an area of similar size inside the vaginal introitus, which Dr. Weber characterized as second-degree burns. Hughes returned for treatment of her burns every other day for two weeks, and thereafter once a week for six to eight weeks.

Hughes asserted claims in her initial complaint under the Mississippi tort law theories of products liability, breach of warranty, negligence, breach of implied warranty of merchantability, and of fitness for a particular purpose. Following Boston Scientific's removal of the action to federal district court, Hughes filed an amended complaint against Boston Scientific. In the amended complaint, Count I for "Products Liability" includes the assertions that "[t]he product failed to contain adequate warnings of dangers or risks which were known or in the light of reasonably available knowledge should have been known to Boston Scientific" and that "the product failed to contain adequate instructions to communicate sufficient information on the dangers associated with, and the safe use of the product." Count II of the amended complaint for "Negligence" includes similar claims that "Boston Scientific failed to provide adequate warnings of dangers or risks which were known or in the light of reasonably available knowledge should have been known to Boston Scientific"; that "Boston Scientific failed to provide adequate instructions to sufficiently communicate information on the dangers associated with the product and its safe use"; and that "Boston Scientific failed to notify the users and consumers of the product of similar problems with, or malfunctions of other units when used for their intended purpose." Count II also charges that Boston Scientific "manufactured and distributed" the product inconsistently with its FDA PMA approval by failing to report serious injuries and malfunctions of the device as defined in the MDR regulations. Hughes also included a separate Count IV for "Negligence Per Se," charging that Boston Scientific violated the FDA regulations governing the safety, effectiveness, and reliability of the HTA.

In the district court, Hughes proceeded on the theory that Boston Scientific failed to comply with the FDA's MDR regulations requiring a manufacturer of a Class III device to report incidents in which the device may have caused or contributed to a death or "serious injury," or malfunctioned in

such a way that would likely cause or contribute to death or serious injury if the malfunction recurred. 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a).[2] The term "serious injury" is defined in the MDR regulations as "an injury or illness that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." 21 U.S.C. § 360i(a)(2); 21 C.F.R. § 803.3. The term "malfunction" is defined to mean "the failure of a device to meet its performance specifications or otherwise perform as intended," with performance specification defined to "include all claims made in the labeling for the device," and intended performance defined as "the intended use for which the device is labeled or marketed . . . ." 21 § C.F.R. 803.3.

Hughes supports her argument that Boston Scientific failed to abide by these reporting regulations with evidence obtained during discovery that Boston Scientific developed an "algorithm" regarding reportable events caused by the HTA according to which Boston Scientific reported some, but not all, burns, as follows:

> (1) First degree burns were not reportable.
> (2) Second degree burns were reportable depending on the extensiveness and intervention required to treat the injury. A second degree burn was MDR reportable if any of the following criteria were met: (a) the burn was classified as extensive by the physician; (b) the burn involved both internal anatomy such as the vagina and cervix and external anatomy such as the vulva, perineum and buttocks; (c) the burn required intervention involving

[2] Hughes has also argued that Boston Scientific did not comply with the additional reporting conditions the FDA included in its PMA approval order for the HTA, pursuant to 21 C.F.R. § 814.81(a)(9), requiring the filing of "Adverse Reaction Reports" concerning "[a]ny adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and (a) has not been addressed by the device's labeling or (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency." The PMA approval order notes that these reporting conditions were largely duplicative of the MDR regulations.

> a medical or surgical procedure that cannot be administered by the patient (such as: systemic antibiotics, debridement, skin grafting, etc.).
> (3) Other second degree burns that can be effectively managed by application of cream or ointment were not considered to be MDR reportable.
> (4) Third degree burns were reportable.

Boston Scientific included this algorithm in its annual reports for the HTA from 2002 to 2008, required by FDA regulation to be filed with the FDA's Center for Devices and Radiological Health ("CDRH"). In response to a 2003 letter from the CDRH inquiring about Boston Scientific's criteria for reportable burns, Boston Scientific included the algorithm in a 2004 letter to the CDRH.

Hughes relies on the expert report of Charles Kyper, a former FDA official. Kyper has given his opinion that Boston Scientific's failure to report certain first and second-degree burns caused by leakage from the HTA device, pursuant to the algorithm, violated the MDR regulations. Hughes further asserts that the FDA itself disapproved of Boston Scientific's reporting practices, relying on the deposition of a Boston Scientific representative, Charles Montgomery, who testified that in 2008 an FDA official "directed" Boston Scientific by letter to abandon the algorithm and to begin reporting more burns caused by the HTA.

After this "direction" from the FDA in 2008, Boston Scientific began reporting more burns caused by the HTA device. Hughes produced evidence that this change in reporting resulted in a sharp increase in the number of reports to the FDA in 2008 and 2009. According to Hughes, evidence from the FDA's MAUDE internet database, which tracks device reports, shows that from 2002 until the time of Hughes's injury in 2006, Boston Scientific submitted 62 reports regarding the HTA, 53 of which involved leaks or burn-related injuries; but following the change in Boston Scientific's reporting criteria at the FDA's

direction in 2008 through July 2009, Boston Scientific filed 495 reports, including 247 of which involved leaks or burn-related injuries.

C.

The district court granted summary judgment to Boston Scientific based on its conclusion that all of Hughes's claims are expressly preempted by § 360k of the MDA as construed by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The district court also rested its decision that Hughes's negligence claim is preempted on *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), in which the Supreme Court held that certain claims are impliedly preempted by § 337a of the MDA. Hughes now appeals the district court's ruling.

II.

This court reviews a district court's award of summary judgment *de novo*, applying the same standards as the district court. *Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 927 (5th Cir. 2006). Summary judgment should be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. PROC. 56(a) (2010). The court must view the record in the light most favorable to the non-moving party in determining whether there is a genuine issue of material fact. *Am Int'l Specialty Lines Ins. Co. v. Canal Indem. Co.,* 352 F.3d 254, 260 (5th Cir. 2003).

III.

We first consider Hughes's argument that her claims are not expressly preempted under § 360k of the MDA. The Supreme Court has twice addressed the preemption of state-law claims regarding medical-device liability pursuant to § 360k, most recently in *Riegel*, 552 U.S. at 312. *Riegel*, like the Court's earlier decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), makes clear that a medical device manufacturer is protected from liability under state-law tort

claims related to a defective or dangerous device to the extent that the manufacturer has complied with federal statutes and regulations. However, *Riegel* and *Lohr* also make clear that a manufacturer is not protected from state tort liability when the claim is based on the manufacturer's violation of applicable federal requirements.

In *Riegel*, the Court established a two-prong test for determining if a state-law tort claim is preempted by § 360k.[3] First, we ask if the FDA has established requirements applicable to the particular device at issue. 552 U.S. at 322. Second, we ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is "different from or in addition to" the federal requirement." *Id*. In setting up this two-prong test, the Court confirmed that state common-law causes of action are considered "requirements" under this test that cannot vary from federal requirements pursuant to § 360k. Specifically, the Court held that New York common-law tort claims of negligence, strict liability, and breach of warranty imposed requirements that were preempted by federal requirements pertaining to medical devices to the extent that these state tort claims required the device "to be safer, but hence less effective, than the model the FDA has approved. . . ." 552 U.S. at 325.

But the plaintiff's claims that the manufacturer had breached an express warranty and was negligent in manufacturing the device "because it did not comply with federal standards" were not before the Court, as the district court had allowed those two claims to proceed without finding them to be preempted

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[3]

> Except as provided in subsection (b) of this section, no 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.

552 U.S. at 316 (quoting 21 U.S.C. § 360k(a)).

and had later dismissed them on summary judgment. *Id*. at 321 n. 2. In fact, the Court clearly noted that its holding only applied to claims that a "device violated state tort law *notwithstanding* compliance with the relevant federal requirements." *Id*. at 330 (emphasis added).

Applying *Riegel's* two-prong test for express preemption to Hughes's claims, we first ask whether the FDA has established requirements applicable to the particular device at issue. *Id*. at 322. *Riegel* established that any Class III device receiving PMA approval by the FDA will satisfy this first prong of the test, *see id*., and Hughes does not dispute this. Thus, we easily conclude that the first prong of *Riegel's* test is satisfied. Moving to the second prong of the test, we must ask whether the state law at issue creates a requirement that is related to the device's safety or effectiveness and is "different from or in addition to" a federal requirement. *Id*. This is the key legal issue disputed by the parties. Thus, we consider below the elements of Hughes's state-law claims to determine whether these claims impose requirements that differ from or are in addition to federal requirements.

A.

It is clear that all of Hughes's state products liability claims that purport to impose liability on Boston Scientific despite Boston Scientific's compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted. *Id*. at 325. We held such traditional state products liability claims to be expressly preempted even prior to *Riegel's* confirmation that these types of claims may not be maintained under § 360k. *Gomez v. St. Jude Medical Daig. Div., Inc.*, 442 F.3d 919, 930-31 (5th Cir. 2006); *Martin v. Medtronic, Inc*., 254 F.3d 573, 575 (5th Cir. 2001).

This includes Hughes's products liability claim for failure to provide adequate warnings or instructions communicating dangers associated with the

HTA to the extent that this Mississippi strict liability claim would question the sufficiency of the FDA-approved labeling, warnings, and instructions for the HTA device or require Boston Scientific to have included different warnings, labels, or instructions with the device. *Gomez,* 442 F.3d at 931 ("To permit a jury to decide [plaintiff's] claims that the information, warnings, and training material the FDA required and approved through PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [the defendant]."). We therefore affirm the district court's judgment with respect to these product liability claims.

B.

We reach a different conclusion, however, with regard to Hughes's claim that Boston Scientific failed to provide adequate warnings or sufficiently communicate information about the risks associated with the HTA device to the extent that this claim is predicated on Boston Scientific's failure to report "serious injuries" and "malfunctions" of the device as required by the applicable FDA regulations. Hughes submits that the Mississippi duty to provide "adequate warnings or instructions," which is imposed on manufacturers pursuant to the products liability code, Miss. Code. Ann. §§ 11-1-63(a)(i)(2), (c)(i), has been construed by Mississippi courts as a duty to provide "reasonable warnings" of risks. *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir. 1992) (citing *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 691 (Miss. 1988)). Hughes further argues that such a failure to warn claim may be pursued not only under a strict products liability theory, but also under a negligence theory, citing *Bennett v. Madakasira*, 821 So. 2d 794, 804 (Miss. 2002) (stating in a drug liability case that the failure to warn inquiry, whether under a strict liability or negligence theory, turns on "the adequacy of the defendant's warnings").

Assuming that a failure to warn claim may be pursued under Mississippi law as Hughes argues, it is clear that such a claim is preempted only to the extent that it purports to impose liability despite Boston Scientific's compliance with FDA regulations. *Riegel*, 522 U.S. at 325; *Gomez,* 442 F.3d at 933. To the extent that Hughes asserts a failure to warn claim based only on Boston Scientific's failure to comply with FDA regulations, however, such a claim is not expressly preempted.

Rather, a failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is "parallel" to federal requirements as defined in *Riegel*, in which the Court stated that "§ 360k does not prevent a State from providing a damages remedy for claims premised on violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." 552 U.S. at 330 (quoting *Medtronic*, 518 U.S. at 495, 513 (O'Connor, J., concurring in part and dissenting in part)).

The discussion of parallel claims originated in the Court's earlier *Lohr* opinion, in which the majority held that "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr,* 518 U.S. at 495, 501. Like Hughes, the *Lohr* plaintiffs asserted a state negligence claim based on the manufacturer's violation of the state duty to warn about dangers of a medical device. *Lohr*, 518 U.S. at 481. The Court held that this claim was parallel, and not preempted. *Id*. at 501.

In our *Gomez* case, a suit seeking recovery for personal injuries caused by a Class III medical device, we relied on *Lohr's* understanding of parallel claims. *Gomez*, 442 F.3d at 932 ("[A] lawsuit that simply parallels or enforces the federal regulatory requirements without "threatening" or interfering with them is not

preempted.") (citing *Lohr*, 518 U.S. at 495).[4] We held that the plaintiff's products liability and negligence claims were preempted to the extent they purported to impose liability notwithstanding the manufacturer's compliance with FDA requirements. *Id*. at 931. We also affirmed the district court's order permitting trial on the plaintiff's negligence claim alleging that the defendant had defectively manufactured the device "because it did not comply with the FDA-approved specifications." *Id*. at 933 ("The district judge properly limited Gomez's negligence claims to a claim that the Angio-Seal used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications.").

Riegel, Lohr, and *Gomez* are consistent in holding that claims for negligent failure to warn or negligent manufacturing of a device are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements. Moreover, this reading of *Riegel* is in accord with post-*Riegel* opinions from other circuits. For instance, the Sixth Circuit held that the plaintiff's negligent manufacturing claim based on a Class III medical device manufacturer's alleged violation of the FDA's Good Manufacturing Practices ("GMP"), which had been incorporated into the PMA regulations, was not preempted. *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 437, 440-42 (6th Cir. June 16, 2010) (unpublished). The Seventh Circuit also recently held in a well-reasoned opinion that state negligence claims premised on a defendant manufacturer's failure to abide by the FDA's approved manufacturing

[4] In *Gomez*, we repeated and endorsed some statements about the meaning of parallel claims from our earlier *Martin* case, another suit seeking recovery for personal injuries caused by a Class III medical device. *Gomez,* 442 F.3d at 931 n. 2. In *Martin*, the court stated that "tort suits based on a manufacturer's failure to follow the FDA's regulations and procedures are not preempted," and further that "common law duties that incorporate the PMA process, such as the general duty to take due care to comply with the PMA process in labeling or manufacturing . . . are not preempted." *Martin*, 254 F.3d at 583, n. 8.

specifications survive express preemption. *Bausch v. Stryker Corp.*, No. 09-3434, __ F.3d __, 2010 U.S. App. LEXIS 26094 (7th Cir. Dec. 23, 2010).

Thus, *Riegel* is no bar to this claim. Hughes's failure to warn claim is comparable to the negligent failure to warn claim in *Lohr* and the negligent manufacturing claims in *Gomez*, *Howard*, and *Bausch*. These authorities make clear that Hughes's claim is not expressly preempted to the extent she asserts that Boston Scientific violated the state duty to warn by failing to accurately report serious injuries and malfunctions of the HTA device as required by the FDA's MDR regulations. The MDR regulations are related to the manufacturer's duty to provide the FDA with information regarding a device's safety and effectiveness, and this information is disseminated to the public.[5] A factfinder could infer that a manufacturer's failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device's risks.

Thus, we are satisfied that Hughes's failure to warn claim is not expressly preempted to the extent that it is based on Boston Scientific's violation of applicable FDA regulations requiring accurate reporting of serious injuries and malfunctions of the HTA device. This claim does not impose additional or different requirements to the federal regulations, but is parallel to the federal requirements.

C.

Hughes next argues that the district court erred in holding that her "negligence per se claim" is preempted. Negligence per se is a legal theory that assists a party to prove that his adversary was negligent. *Gray v. Beverly*

[5] The summary judgment evidence indicates that manufacturers provide these reports to the FDA, the FDA then disseminates the reports to the public, and the reports are then relied upon by physicians and authors of medical journals in comparing the relative safety of medical devices. *See* discussion of causation *supra* Section V.

Enterprises-Miss., Inc., 390 F.3d 400, 407 (5th Cir. 2004) ("Negligence per se . . . is a theory by which statutes are used to establish the appropriate standard of care.") (Mississippi tort action); s*ee also* Fowler V. Harper, et al., HARPER, JAMES, AND GRAY ON TORTS, § 17.6, 709, n. 16 (3d ed. 2007) ("In a substantial number of jurisdictions such a [statutory] violation is held to be evidence of negligence to be weighed by the jury.") (citing state cases including *Simpson v. Boyd*, 880 So. 2d 1047, 1053 (Miss. 2004)).[6]

As we have explained, the doctrine of preemption is designed to foreclose a state cause of action that imposes different or additional requirements on a defendant when compared to federal requirements. The only issue presented to us on this appeal is whether the district court correctly determined that Hughes's suit is preempted. Thus, Boston Scientific's preemption defense only requires us to decide which of Hughes's state law causes of action are foreclosed under § 360k. Because negligence per se is a theory or "doctrine" that assists a party in proving negligence rather than an independent state tort action, whether that doctrine will apply at trial does not affect Hughes's ability to assert her negligent failure to warn cause of action under § 360k. We need not decide, therefore, whether Hughes will be able to invoke the doctrine of negligence per se as a matter of Mississippi law to establish that Boston Scientific breached the state duty to warn by failing to report serious injuries and malfunctions of the HTA device as required by the MDR regulations. In other words, because Hughes's claim is not foreclosed by § 360k, Hughes is not foreclosed by §360k

[6] The parties agree that the Mississippi law or "doctrine" of negligence per se generally operates so that when a defendant has violated a particular statute or regulation, the injured party is entitled "to an instruction that the party violating it is guilty of negligence." *Thomas v. McDonald*, 667 So. 2d 594, 596 (Miss. 1995); *Simpson*, 880 So. 2d at 1053. To recover, the plaintiff must also show "he is a member of the class that the statute was designed to protect and that the harm suffered was the type of harm which the statute was intended to prevent" and that the violation "proximately caused" the injury. *Thomas,* 667 So. 2d at 596; *Simpson*, 880 So. 2d at 1053.

from arguing at trial that the doctrine of negligence per se is available to assist her in proving her claim. *See Gomez*, 442 F.3d at 933 (referring to the plaintiff's negligent manufacturing claim surviving preemption as one for possible "negligence per se" under Louisiana law); *Bausch*, No. 09-3434, __ F.3d __, 2010 U.S. App. LEXIS 26094 at *13 (noting with regard to the non-preempted negligent manufacturing claim that "Illinois treats a violation of a statute or ordinance designed to protect human life or property as prima facie evidence of negligence . . ."); *Sulzer*, 382 F. App'x at 442 (Plaintiff's "negligence per se claim for GMP violations is not preempted.").

Boston Scientific makes a related argument, with which the district court agreed, that §360k should prevent Hughes from invoking the doctrine of negligence per se because a defendant is permitted by Mississippi law to argue the reasonableness of its actions as a rebuttal to the presumption of negligence that arises from violation of a statute or regulation. *See*, *e.g., Alabama Great S. R.R. Co. v. Lee*, 826 So. 2d 1232, 1236 (Miss. 2002). Boston Scientific contends that this reasonableness defense constitutes an "additional" or "different" duty under § 360k. We disagree because reasonableness is an optional defense to rebut the presumption of negligence that arises from the defendant's violation of a statute or regulation in Mississippi (and in most states) that a defendant may present to narrow the scope of liability. *See id.* It is strictly up to the defendant whether "reasonableness" is injected in the case. Our reaction to Boston Scientific's argument is consistent with the Supreme Court's statement in *Lohr* that "[w]hile 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 preemption of a state rule insofar as it duplicates the federal

rule." *Lohr*, 518 U.S. at 495.[7] There is nothing in *Riegel* suggesting that the Supreme Court's view on this issue has changed. Therefore, guided by the Court's comments, we conclude that invoking the negligence per se doctrine to support a negligence claim that is otherwise parallel to federal requirements is not expressly preempted.[8]

D.

Boston Scientific argues next that permitting the jury to determine whether Boston Scientific violated the FDA's reporting requirements would lead to the possible imposition of different or additional state requirements. Boston Scientific contends that the FDA never made a "formal" finding that Boston Scientific failed to comply with the MDR regulations or initiated an enforcement action against Boston Scientific and that such a "formal" action by the FDA must be considered an "implicit precondition" to a parallel suit because a jury should not be permitted, in the first instance, to make such a finding.

We are persuaded that any additional "formal" finding or enforcement action by the FDA is not an "implicit precondition" to suit under the facts of this case. No controlling authority holds or implies that any particular type of formal action by the FDA is a prerequisite to a parallel state suit. To the contrary, in *Gomez,* this court permitted the plaintiff to prove non-compliance with the

[7] The Court repeated this "strange reason" comment in *Bates v. Dow-Agro Sciences, LLC*, 544 U.S. 431, 448 n.23 (2005) (regarding preemption under the Federal Insecticide, Fungicide, and Rodenticide Act).

[8] One of the reasons given by the district court for holding Hughes's negligence per se "claim" to be preempted is that the FDA regulations are "administrative," and the district court further suggested that allowing such a claim is "contrary to Congressional intent." *Hughes v. Boston Sci. Corp.*, 669 F. Supp. 2d 701, 712-13 (S.D. Miss. 2009). For the reasons stated above, § 360k does not preempt use of the negligence per se doctrine. Therefore, the district court erred in finding that principles of preemption applied to affect the use of this doctrine. Implied preemption is also inapplicable to bar use of negligence per se for the same reasons. However, we express no opinion on whether Hughes may utilize the doctrine of negligence per se based on violation of the FDA regulations at issue in this case as a matter of Mississippi tort law because this question is not before us.

applicable FDA manufacturing specifications without requiring her to show that the FDA made a formal finding or undertook an enforcement. *Gomez*, 442 F.3d at 933. The Sixth Circuit also permitted state negligence claims based on violations of FDA manufacturing specifications without a formal FDA finding of non-compliance. *Howard*, 382 F. App'x at 440-42.

At best, the miscellaneous district court opinions cited by Boston Scientific suggest that *conclusory* allegations of an FDA regulatory violation are impermissible. But Hughes's allegations are not conclusory. She has presented evidence that supports the view that Boston Scientific violated the plain text of the MDR regulations. The regulations required Boston Scientific to report any time the device "may have caused or contributed to death or serious injury," or malfunctioned in a manner that would "would be likely to cause or contribute to a death or serious injury in the malfunction were to recur." 21 U.S.C. § 360i(a)(1)(A)-(B); 21 C.F.R. § 803.50(a). The term "serious injury" is defined as "an injury or illness that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." 21 C.F.R. § 803.3. This definition is mandated by statute. 21 U.S.C. § 360i(a)(2). Hughes has offered expert testimony that some of the burns Boston Scientific failed to report necessitated medical or surgical intervention to preclude permanent injuries. Boston Scientific's failure to report such burns would support a finding of violation of the plain text of the regulation. *Id.*; 21 C.F.R. § 803.3.

Similarly, the word "malfunction" is defined to mean "the failure of a device to meet its performance specifications or otherwise perform as intended," with performance specification defined to "include all claims made in the labeling for the device," and intended performance defined as "the intended use for which the device is labeled or marketed . . . ." 21 § C.F.R. 803.3. Hughes's

expert has stated his opinion that Boston Scientific's failure to report burns caused by leakage from the HTA violated this regulation because the risk of such burns was not reflected on the HTA's labeling. The summary judgment evidence supports this plain interpretation of the term "malfunction," because the HTA's labeling available to Hughes in 2006 apparently warned only about burns caused by user error, not burns caused by leakage from the device in the absence of user error. According to Hughes's summary judgment evidence, her burn was caused by leakage from the HTA device not arising from user error, and some of the other unreported burns may have been due to similar leaks not implicating user error.

We therefore conclude that the evidence is sufficient to allow the jury to determine that Boston Scientific failed to report serious injuries and malfunctions caused by the HTA as required by the MDR regulations. Furthermore, any danger that the jury in this case may apply the plain terms of the MDR regulations in a different or more stringent manner than the FDA intended is considerably mitigated by the summary judgment evidence indicating that the FDA disapproved of Boston Scientific's reporting practices. Charles Montgomery, Boston Scientific's representative, testified during deposition that an FDA official "directed" Boston Scientific via letter in 2008 to abandon the algorithm and to begin reporting all burns caused by the HTA.[9] Montgomery testified that the FDA told Boston Scientific that when information regarding a burn is "ambiguous" as to whether the burn requires medical treatment or intervention, the burn must be reported. Accordingly, once Boston Scientific changed its reporting practices consistent with the FDA's direction in 2008, Boston Scientific began reporting significantly more burns caused by the HTA.

[9] This letter was discussed at length in the deposition but we have been unable to locate it in the record.

This evidence strongly suggests that the FDA concluded that Boston Scientific's algorithm failed to satisfy the MDR regulations requiring reports of "serious injuries." The FDA's 2008 letter appears to be consistent with how the FDA usually addresses noncompliance with MDR obligations. Kyper asserts in his expert report that the FDA often relies on voluntary measures to remedy reporting violations rather than initiate expensive and time-consuming enforcement actions or PMA withdrawals. Boston Scientific has not directed the court to any regulation or statutory provision requiring the FDA to respond to a violation in any particular manner. Rather, the regulations support Hughes's contention that the FDA has the discretion to undertake any enforcement method it chooses to remedy violations of the MDR regulations, including voluntary measures. Thus, permitting the jury in this action to find that Boston Scientific violated these regulations, consistent with the FDA's 2008 letter to Boston Scientific, is supported by *Riegel*, *Lohr*, and *Gomez*, all of which make clear that a state may impose "additional remedies" for violations of FDA regulations beyond those which the FDA imposes. *See, e.g., Riegel,* 552 U.S. at 330.

Moreover, permitting the jury to make this finding would not conflict with any contrary FDA decision. Based upon its inclusion of the reporting algorithm in its annual reports to the FDA, Boston Scientific argues that the FDA actually did approve the algorithm before challenging it in 2008. But Boston Scientific cannot point to any decision or communication by the FDA expressly or impliedly approving the algorithm. Nor can Boston Scientific cite any authority establishing that the FDA's silence should be treated as approval of the algorithm. To the contrary, some courts have rejected similar arguments. *See, e.g., In re Bextra & Celebrex Mktg. Sales Practice & Prod. Liab. Litig.*, No. M:05-1699 CRB, 2006 U.S. Dist. LEXIS 95500, *70-71 (N.D. Cal. Aug. 16, 2006) (defendant drug manufacturer "cite[d] no authority for its assertion that the

FDA's silence as to a particular advertisement means that the FDA 'necessarily determined' that the advertisement was not deceptive . . . ."); *accord In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 375 (E.D.N.Y. 2010). Based on consideration of this evidence in the light most favorable to Hughes, we cannot conclude that the FDA approved Boston Scientific's algorithm before disapproving of it in 2008. For all these reasons, we reject Boston Scientific's assertion that any additional "formal" finding or action by the FDA is a prerequisite to this parallel suit.

IV.

We next consider Hughes's argument that the district court erred in holding that her negligence claim[10] was preempted under § 337a of the MDA, as construed in *Buckman*, 531 U.S. at 341. The suit in *Buckman* was for personal injuries suffered from orthopedic bone screws in patients' spines. *Id.* The plaintiffs alleged that the manufacturer made fraudulent representations to the FDA about the screws' potential use in the spine in order to receive FDA approval. *Id.* The plaintiffs argued that but for this fraud, the FDA would not have approved the screws and the plaintiffs would not have been injured. *Id.* at 347. The Court held that allowing the plaintiff to pursue a suit based on a "fraud-on-the-FDA" theory conflicted with the federal regulatory scheme by disrupting the "delicate balance of statutory objectives," and was therefore impliedly preempted under 21 U.S.C. § 337(a).[11] *Id.* at 347-53. The majority made clear, however, that some parallel state claims survive preemption by the MDA, stating "it is clear that the [*Lohr*] claims arose from the manufacturer's

[10] The district court repeatedly referred to the implied preemption of Hughes's "negligence per se claim."

[11] § 337(a) states that "[e]xcept as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States."

alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements," whereas "[i]n the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements." *Id*. at 352-53 (citing *Lohr*, 518 U.S. at 481). The majority also distinguished the "fraud-on-the-FDA" theory from the "traditional state tort law" claims that were not preempted in *Silkwood v. Kerr-McGee Corp*., 464 U.S. 238 (1984). *Id*. at 351-52.

Hughes's claim is not analogous to the "fraud-on-the-FDA" theory in *Buckman*. The plaintiffs in *Buckman* were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations; the plaintiffs did not assert violation of a state tort duty. In contrast, Hughes is asserting a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of product. She seeks to prove Boston Scientific's breach of the state duty by showing that Boston Scientific violated the FDA's MDR regulations. Because Hughes is asserting a recognized state tort claim, her claim is comparable to the tort claims in *Silkwood* and *Lohr* that *Buckman* recognized as surviving implied preemption. The Seventh Circuit reached a similar conclusion, holding that the plaintiff's negligence claims based on the manufacturer's violation of the FDA's specifications were not impliedly preempted under *Buckman* because the plaintiffs were asserting breach of a "recognized state-law duty" rather than "an implied right of action under federal law." *See Bausch,* No. 09-3434, __ F.3d __, 2010 U.S. App. LEXIS 26094 at *28.

Notably, Hughes's claim does not depend on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue, as in *Buckman*. Moreover, Boston Scientific's interpretation of *Buckman* barring this otherwise parallel state claim is inconsistent with the Supreme Court's reasoning in *Riegel*, decided long after *Buckman*. *Riegel* unequivocally held that parallel state claims survive a

defendant's preemption defense under the MDA because states may impose an additional "damages remedy for claims premised on violation of FDA regulations." *Riegel*, 522 U.S. at 330. Our conclusion in this respect is also supported by our decision in *Gomez,* decided years after *Buckman,* in which we permitted a negligence claim for defective manufacturing to proceed. *Gomez*, 442 F.3d at 933. Thus, we hold that Hughes's failure to warn claim is not impliedly preempted.

V.

Finally, Boston Scientific argues that Hughes failed to present enough evidence to create a genuine issue of material fact regarding causation. A Mississippi negligence claim, including one relying on the rule of negligence per se, can only succeed if the plaintiff can prove that the defendant's violation of a statute or regulation caused the plaintiff's injury. *See, e.g., Thomas*, 667 So. 2d at 596. Because the district court held that all of Hughes's claims are preempted, the district court did not address causation.

Hughes's primary causation theory is that if Boston Scientific had reported the true number of injuries and malfunctions related to burns caused by the HTA, this information would have appeared on the FDA's MAUDE internet database and in medical journals, and with this information Dr. Weber would not have recommended the HTA to Hughes for treatment, nor would Hughes have chosen the HTA as a treatment option.[12] However, we decline Boston

[12] Hughes has asserted other causation theories which are untenable. She asserts that had Boston Scientific properly reported all burns (1) the FDA would have taken some regulatory action against the HTA, including but not limited to removing the HTA from the market; and (2) the HTA labels or user manual would have warned of the risk of burns associated with use of the HTA. The first theory is entirely speculative, *Rod v. Home Depot USA, Inc.*, 931 So. 2d 692, 695 (Miss. Ct. App. 2006) (holding that causation cannot be proved based on speculation), and could impermissibly allow the jury to question the FDA's decision to approve the device for the market. *Buckman,* 531 U.S. at 347-53. The second theory is unacceptable because Hughes cannot ask the jury to second-guess the HTA's label or user manuals, which were specifically approved by the FDA. *Gomez*, 442 F.3d at 931.

Scientific's invitation to consider whether it is entitled to summary judgment on this issue in this appeal. We are persuaded that we should permit the district court to consider this argument in the first instance on remand.

VI.

For the above reasons, we affirm that part of the district court's judgment dismissing Hughes's state-law claims as preempted except for Hughes's failure to warn claim. We conclude that Hughes's failure to warn claim is neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on Boston Scientific's violation of FDA regulations with respect to reporting burns caused by the HTA.

Accordingly, we affirm the district court's dismissal on summary judgment of all claims Hughes asserted except for Hughes's failure to warn claim. We vacate the order insofar as it dismisses this claim and remand this claim to the district court for further proceedings consistent with this opinion.

AFFIRMED in part, VACATED in part, and REMANDED.