No. 09-60925

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

JAN HUGHES,

Plaintiff-Appellant,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant-Appellee.

On Appeal from a Final Judgment of the United States District Court for the Southern District of Mississippi, No. 08-cv-00079, Hon. Keith Starrett, U.S.D.J.

REPLY BRIEF FOR PLAINTIFF-APPELLANT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes and Regulations:

Other:

INTRODUCTION AND SUMMARY OF ARGUMENT

The claims at issue in this appeal, and Ms. Hughes's arguments concerning preemption, are straightforward. Ms. Hughes claims that she suffered serious burns as a result of Boston Scientific's failure to report adverse events involving the Hydro ThermAblator. That failure, she claims, violated requirements imposed on Boston Scientific by FDA regulations and the conditions under which its device received premarket approval, and also violated Boston Scientific's duty to provide Ms. Hughes and her doctor with adequate warnings about the dangers of the device. Ms. Hughes's claims are not preempted under 21 U.S.C. § 360k(a) because they do not rest on any requirements that differ from or are in addition to those imposed by federal law on Boston Scientific. Rather, the claims are based on state-law duties that parallel requirements of federal law, and the Supreme Court held in both *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), that such claims are not expressly preempted by § 360k(a). Boston Scientific attempts to evade the import of *Lohr* and *Riegel* by engrafting new limitations on their holdings or imposing additional requirements that parallel claims must meet to avoid preemption, but its efforts are unavailing.

Nor are Ms. Hughes's claims barred by implied preemption under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Although Boston Scientific strains to give *Buckman* the broadest possible reading, the decision's

core holding is that claims that a defendant violated duties owed only to the FDA under federal law, such as the "fraud-on-the-agency" claims at issue in *Buckman* itself, are preempted. *Buckman* does not hold that a state may not give content to traditional tort duties owed by medical device manufacturers to patients by referring to federal-law requirements that serve purposes similar to those of common-law duties of care. Reading it to preempt such claims would be contrary to the longstanding presumption against preemption of state common law.

Finally, this Court should reject Boston Scientific's fallback argument that it is entitled to summary judgment on the issue of causation if Ms. Hughes's claims are not preempted. That issue was not reached by the district court and is best left for remand. Should the Court nonetheless choose to address it, it should reject Boston Scientific's argument because the record contains direct evidence that Ms. Hughes and her doctor would have chosen not to use the Hydro ThermAblator had they been aware of the risks that were concealed from public view by Boston Scientific's violation of its reporting obligations. Boston Scientific's arguments that that evidence should be disregarded are contrary to the established law of this Circuit, *see Kennett-Murray Corp. v. Bone*, 622 F.2d 887 (5th Cir. 1980), and if the evidence is credited, as it must be for purposes of summary judgment, there is a genuine issue of fact for trial as to causation.

ARGUMENT

I. Section 360k(a) Does Not Preempt Ms. Hughes's Claims to the Extent That They Involve Boston Scientific's Failure to Report Adverse Events, Because Such Claims Do Not Rest on State-Law Requirements That Differ from Requirements of Federal Law.

Boston Scientific concedes that even for devices that have received premarket approval, § 360k(a) does *not* preempt state-law claims against a medical device manufacturer based on duties that parallel federal requirements because such claims do not impose requirements that are "different from, or in addition to" those imposed by federal law. And for purposes of this appeal, Boston Scientific does not appear to take issue with the proposition that, as a matter of Mississippi state law, the tort-law principles of failure to warn and negligence per se provide a right of action to a person who is injured when a device manufacturer's noncompliance with federal reporting standards results in a failure to warn of the risks of using a device and causes injury to a patient. Boston Scientific nonetheless argues that § 360k(a) preempts such claims because, in its view, the claims would impose different or additional requirements on it even assuming that its actions in fact violated applicable federal regulations. Each of Boston Scientific's arguments, however, rests on a misreading of § 360k(a) as definitively construed by the Supreme Court in *Lohr* and *Riegel*.

A. The Absence of Formal FDA Findings That Boston Scientific Violated Federal Requirements Does Not Mean That Section 360k(a) Preempts Ms. Hughes's State-Law Claims.

Boston Scientific argues that Ms. Hughes's state-law claims do not parallel federal requirements because the FDA has never formally found that Boston Scientific violated the FDA's adverse event reporting requirements. In the absence of such a finding, Boston Scientific asserts that imposing liability on it would effectively impose requirements upon it that are in addition to those that have been imposed by the FDA. In other words, Boston Scientific contends that § 360k(a) does not permit states to impose liability for *conduct* that violated federal requirements, but only for conduct that the FDA has *found* to violate federal requirements.

According to Boston Scientific, a number of district courts have held that an FDA finding of a violation of federal requirements is "an implicit pre-condition to a negligence *per se* claim based on violation of a federal regulation." App'ee Br. 25 (citing *Ilarraza v. Medtronic, Inc.*, __ F. Supp. 2d __, 2009 WL 5245630 (E.D.N.Y. Dec. 28, 2009), *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009), and *Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008)). None of these decisions, however, holds or implies any such precondition. *Purcel* allowed a parallel state-law claim to proceed in circumstances where the evidence of a violation of federal standards *included* an enforcement

action brought by the FDA, but nowhere did the court suggest that FDA enforcement was a precondition to such an action. *Ilarraza* and *Horowitz* held that generalized or conclusory allegations of a violation of federal regulations did not suffice to demonstrate that state-law claims paralleled federal requirements, but neither held that an allegation that the FDA had found a violation was required.[1] Indeed, the court in *Horowitz* recognized that "[a]ll that is required for a state law claim to bypass preemption is that it not be in conflict with the federal regulation," 613 F. Supp. 2d at 281 n.4—a statement that cannot be squared with the idea that an FDA enforcement action is a necessary, additional prerequisite to maintenance of a parallel state-law claim under § 360k(a).

More important, it is the terms of the statute and the construction given it by the Supreme Court and this Court that are controlling here, not the views of district courts. Section 360k(a) prevents states from imposing "requirements" on manufacturers—*i.e.*, telling them what they must do or cannot do—that go beyond federal requirements. But where the requirements are the same, nothing in the language of § 360k(a) suggests that states can enforce those requirements, or

[1] Although a merely conclusory allegation of a violation of federal requirements may not suffice to avoid preemption of an assertedly parallel state-law claim, there is nothing "conclusory" about Ms. Hughes's claims that Boston Scientific violated federal requirements. Rather, those claims are based on undisputed evidence that Boston Scientific used a matrix that resulted in the failure to report large numbers of burn cases as adverse events.

provide a remedy for their violation, only when the federal government has already done so. Indeed, the Supreme Court *unanimously* agreed in *Lohr* that "[s]ection 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part); *see also id*. at 495 (majority opinion).

If an actual FDA finding of a federal-law violation were a necessary prerequisite to maintaining a parallel state-law claim under § 360k(a), the outcome in *Lohr* would have been different because there is no indication in that case that the agency had ever found that the manufacturer had violated the federal regulations that the plaintiffs alleged it had transgressed. Similarly, in *Bates v. Dow AgroSciences LLC*, where the Court held that the substantively identical preemption clause of FIFRA (7 U.S.C. § 136v(b)) did not preempt state-law claims based on conduct that violated federal law, the Court permitted parallel claims to proceed in the absence of any indication that the federal agency (there, EPA) had found violations of the relevant federal-law requirements. 544 U.S. 431, 447-52 (2005).[2]

[2] In *Bates*, the United States argued unsuccessfully for preemption of the parallel claims asserted in the case, but conceded that state-law claims would not be preempted if the EPA had found a violation of federal requirements, thus making clear that there had been no such finding in *Bates*. *See* Brief for the United States as Amicus Curiae Supporting Respondent, *Bates v. Dow AgroSciences LLC*, No. 03-388, at 24 n.12 (filed Nov. 2004), *available at* http://www.justice.gov/osg/briefs/2004/3mer/1ami/2003-0388.mer.ami.pdf.

Likewise, this Court in *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001), approved the district court's decision to allow parallel state-law claims against a device manufacturer to proceed because "tort suits based on a manufacturer's failure to follow the FDA's regulations and procedures are not preempted." *Id.* at 583. The Court endorsed the district court's holding that claims that the manufacturer "did not adequately comply with the PMA process" were not preempted, *id*. at 585, despite the absence of any indication that the FDA itself had found that the manufacturer did not comply with the federal requirements. And in *Gomez v. St. Jude Medical Daig Division, Inc.*, 442 F.3d 919 (5th Cir. 2006), this Court not only held that parallel state-law claims based on the manufacturer's alleged violation of the federally required specifications for the device were not preempted, but it found the evidence of such a violation sufficient to go to a jury without even hinting that a part of the showing required to avoid preemption was that the FDA itself had found a violation of the federal requirements. *See id.* at 932-36. Indeed, the court's detailed recitation of the facts concerning the alleged violation of manufacturing specifications leaves no doubt that there had been no FDA finding of a violation.

Boston Scientific's contention that allowing parallel state-law claims to proceed in the absence of an actual finding of a federal-law violation by the federal agency would somehow improperly displace federal authority is not only without

foundation in the terms of the statute, which expressly permits states to enforce requirements as long as they are not different from or in addition to federal requirements; the argument was also explicitly rejected by the Supreme Court in *Bates*. There, the Court addressed the argument—the same one Boston Scientific advances here—that permitting state common-law actions based on duties that paralleled federal requirements would allow juries in fifty states to create a "crazy-quilt" of requirements by displacing the federal agency's power to "authoritatively" interpret the scope of federal law. 544 U.S. at 448. The Court held that that argument could not be squared with *Lohr* or with the "clear text" of the statute, which, like § 360k(a), permits the enforcement of state-law requirements as long as they are not different from or additional to those imposed by federal law. *Id.* at 448-49. In addition, the Court pointed out that enforcing federal requirements through state-law remedies would "aid, rather than hinder" the effectiveness of federal law, *id*. at 451, and it discounted the likelihood that "properly instructed juries" would often apply federal requirements inconsistently, interfere with the authority of the federal agency, or subject manufacturers to "difficulties beyond those regularly experienced by manufacturers of other products that every day bear the risk of conflicting jury verdicts." *Id.* at 452.

Boston Scientific's assertion that the FDA's failure to take enforcement action against it or formally order the ThermAblator withdrawn from the market

means that Boston Scientific was in compliance with federal requirements is, moreover, implausible. The FDA often proceeds not by bringing formal proceedings against violators of the laws regulating drugs and medical devices, but by pressuring companies that have violated its requirements to correct their noncompliance "voluntarily." *See* R.2151-60 (expert report of Dr. Kyper). Here, it is undisputed that Boston Scientific had adopted a "matrix" to determine whether to report burns attributable to malfunctions of the ThermAblator, under which large numbers of serious incidents (including burns such as those suffered by Ms. Hughes) would not be reported to the FDA; and that, following an FDA audit of Boston Scientific's reporting practices, the company abandoned the matrix and began reporting all burns, including those that it had previously not reported.[3]

That the FDA, having pressured the company into abandoning the matrix and retroactively correcting its reports, chose not to take any formal enforcement action, hardly suggests that Boston Scientific was not in violation.[4] Indeed, Boston

[3] Boston Scientific now asserts that *not* all burns are reported even today, App'ee Br. 30, but in the district court proceedings it stated unequivocally that "[a]ll burns are now reportable to the FDA." R.2171 (Boston Scientific's supplemental interrogatory responses); *accord* R.2174 (Boston Scientific's 30(b)(6) deposition testimony).

[4] Boston Scientific's assertion that it included some information about all burn cases in its annual reports, App'ee Br. 27, is irrelevant to whether it violated the adverse event reporting requirement. Annual reports are submitted to a different division of the FDA than adverse event reports, *see* R.2150 (expert report of Dr. Kyper), and burn cases referred to only in annual reports would not be

Scientific's 30(b)(6) deponent testified that the agency had "directed" Boston Scientific to change its reporting algorithm, R.2174, which hardly supports Boston Scientific's contention that the agency believed Boston Scientific was in compliance with the applicable requirements. And although Boston Scientific implies that the agency actually found that it was *not* in violation (*see* App'ee Br. 27-28), none of the FDA actions or communications referred to in Boston Scientific's brief purported to approve of Boston Scientific's reporting practices or expressed a finding that they actually complied with federal law. Similarly, that the FDA never withdrew premarket approval of the ThermAblator cannot be taken as a sign that Boston Scientific was in full compliance with federal requirements when, as Boston Scientific acknowledges, it ultimately recalled the version of the device that injured Ms. Hughes.[5] The most that can be concluded from the FDA's inaction is that, with the version of the device the injured Ms. Hughes now off the market, the agency has in its discretion chosen not to pursue possible violations by Boston Scientific.

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included in the FDA's publicly accessible adverse event database and thus would not signal potential dangers of the device to members of the medical community and the public.

[5] Although the recall may not be admissible to prove that Boston Scientific was liable, it surely is admissible to *rebut* Boston Scientific's argument that the FDA's failure to take the product off the market means that the FDA concluded that Boston Scientific was in compliance with federal law.

B. Ms. Hughes's Failure to Warn and Negligence Per Se Claims Do Not Impose Requirements "Different from or in Addition to" Federal Requirements.

Echoing the district court, Boston Scientific asserts that Ms. Hughes's claims of failure to warn and negligence per se based on its failure to report adverse incidents in violation of federal regulations would impose different or additional requirements on it because it might still *avoid* liability under Mississippi law by establishing that its conduct was reasonable.[6] In other words, Boston Scientific contends that Mississippi product liability law is preempted because the requirements it would impose, while parallel to the federal requirements, are less onerous in the sense that a state-law tort remedy would not always be available for a violation of the federal requirements.

[6] Boston Scientific's argument that Mississippi common law would allow a defendant in a negligence per se case to excuse a violation of a statute as reasonable appears to rest on a misreading of Mississippi case law. The Mississippi Supreme Court has held that in a negligence per se case, "[w]hen a statute is violated, *the injured party is entitled to an instruction that the party violating is guilty of negligence,* and if that negligence proximately caused or contributed to the injury, then the injured party is entitled to recover." *Thomas v. McDonald,* 667 So. 2d 594, 596 (Miss. 1995) (emphasis added). The decision on which Boston Scientific principally relies, *Alabama Great Southern Railroad v. Lee.* 826 So. 2d 1232 (Miss. 2002), is not a negligence per se case, but a case where the Mississippi Supreme Court held the doctrine of negligence per se *inapplicable* because the relevant statute expressly provided that a violation did not by itself constitute negligence. *Id*. at 1237. Regardless of the proper answer to this state-law question, there is no preemption of negligence per se claims under § 360k(a) for the reasons stated in the text.

Boston Scientific has no response to our opening brief's demonstration that the district court's reasoning in this respect (which is in turn based on an unpublished decision of another district court) is directly contrary to the Supreme Court's express holding in *Lohr* that "additional elements" in state common-law claims, such as the requirement that a defendant's conduct be "unreasonable," are not preempted by § 360k(a) because, if anything, they "would make the state requirements narrower, not broader, than the federal requirement." 518 U.S. at 495. The Supreme Court reiterated this point in *Bates*, 544 U.S. at 447 n.23, and in *Riegel* it cited the same passage from *Lohr* with approval. 552 U.S. at 330. That Boston Scientific merely parrots the district court's analysis without attempting to explain how it can be squared with the Supreme Court's express rejection of the same argument in *Lohr* and *Bates* is telling.[7] The Supreme Court's decisions definitively establish that a claim that Boston Scientific's failure to comply with FDA reporting requirements constituted a failure to warn under Mississippi

[7] Indeed, one of the decisions Boston Scientific itself relies on heavily for other purposes, the district court decision in *Horowitz v. Stryker Corp.*, goes out of its way to reject, as incompatible with *Riegel*, Boston Scientific's theory that a state-law claim is not parallel simply because state common-law doctrines have some elements that are, in the abstract, different from the federal regulations. *See* 613 F. Supp. 2d at 281 n.4 (noting that the reasoning of *Bausch v. Stryker Corp.*, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008), is "at odds with" *Riegel*).

common law is not preempted as long as Mississippi law would not require Boston Scientific to do more than federal law requires.[8]

C. Boston Scientific's Arguments That Negligence Per Se Claims Are Always Preempted or That They Are Preempted If Based on Violations of "Administrative" Requirements Are Unfounded.

Boston Scientific asserts that a number of lower courts have rejected negligence per se claims based on violations of FDA requirements, and it argues (based on a decision of an intermediate Tennessee state court) that even if some negligence per se claims may escape preemption, only those based on breaches of "substantive" as opposed to "administrative" requirements may proceed. However, the great majority of the cases Boston Scientific cites did not hold negligence per se claims *preempted*, but instead held only that particular alleged regulatory violations did not, as a matter of *state* law, provide a basis for claims of negligence per se (under the laws of states not involved in this case).[9] Indeed, some of those

[8] The result is the same whether the breach of the standard of care is established simply by the fact of a violation of federal law under a negligence per se theory or whether the jury independently determines that Boston Scientific's noncompliance with the federal requirements was negligent or provided an unreasonable warning. In neither case is the claim preempted because in neither case does the state-law duty demand more from Boston Scientific than that it make the reports required by federal law.

[9] *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 790 (3d Cir. 1999); *Vanderwerf v. SmithKlineBeecham Corp.*, 414 F. Supp. 2d 1023 (D. Kan. 2006); *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591 (W.D. Tex. 2002); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1287 (N.D. Okla.

decisions acknowledged that if a claim of negligence per se were available under the laws of the state in question, it would not be preempted by § 360k(a) because it would impose requirements parallel to federal ones. Thus, the court in *Vanderwerf v. SmithKline Beecham Corp.* stated that "a state by legislation or through common law *can* create a private remedy for violations of the FDCA" but held that Kansas had not done so for the violations claimed in that case. 414 F. Supp. 2d at 1028 (emphasis added). Similarly, the court in *Cali v. Danek Medical, Inc.*, citing *Lohr*, recognized that "the FDCA would not preempt such a claim [of negligence per se] if it was recognized under Wisconsin law." 24 F. Supp. 2d at 953.

The *Cali* court's recognition that claims of negligence per se are not preempted by § 360k(a) flows ineluctably from the Supreme Court's square holding in *Lohr*—a holding in which all nine Justices concurred—that the statutory language at issue allows a state to "create a cause of action [that] seeks to enforce an FDCA requirement." 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part); *accord id*. at 495 (majority opinion). The Court similarly held in *Bates* that a statute prohibiting state requirements that are different from or

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2000); *Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353 (M.D. Fla. 1999); *Cali v. Danek Med., Inc.*, 24 F. Supp. 2d 941 (W.D. Wis. 1998); *Friedlander v. HMS-PEP Prods., Inc.*, 485 S.E.2d 240 (Ga. Ct. App. 1997); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352 (Ill. 1996); *Osburn v. Danek Med., Inc.*, 520 S.E.2d 88 (N.C. Ct. App. 1999), *aff'd*, 530 S.E.2d 54 (N.C. 2000); *Bish v. Smith & Nephew Richards, Inc.*, 2000 WL 1294324 (Tenn. Ct. App. Aug. 23, 2000).

additional to federal ones does not bar states from "providing a remedy" for violations of federal requirements. 544 U.S. at 448. And in *Riegel*, the Court reiterated that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." 552 U.S. at 330. If, as the Supreme Court stated in *Lohr*, *Bates*, and *Riegel*, a state is free to provide a right of action as a direct remedy for a violation of federal requirements, surely it may also, in an action based on a breach of the traditional common-law duty to warn, incorporate federal requirements as the applicable standard of care through the doctrine of negligence per se. In both instances, the state has provided a remedy for conduct that violates federal requirements, without imposing any additional or conflicting requirements on the manufacturer. *Lohr*, *Bates*, and *Riegel* definitively hold that such remedies are not preempted by § 360k(a), and it is their holdings, not the views of a handful of district courts, that are controlling.

Boston Scientific's proffered substantive/administrative distinction is likewise in error. Boston Scientific offers no response to the point made in our opening brief that § 360k(a)'s text does not distinguish between "substantive" and "administrative" requirements. Rather, the statute's preemptive effect turns on whether a federal requirement is "applicable" to a device, 21 U.S.C. § 360k(a)(1), and on whether state requirements relating to the device's safety and efficacy are "different from, or in addition to" the federal requirement. *Id.* If they are not, then

they are not preempted, regardless of whether the federal requirement is characterized as "substantive" or "administrative." That the substantive/administrative distinction cannot be squared with the criteria for preemption under § 360k(a) is not surprising because the decision on which Boston Scientific relies for the distinction's existence, *King v. Danek Medical, Inc.*, 37 S.W.3d 429 (Tenn. Ct. App. 2000), *was not based on preemption*: It was a decision about the circumstances under which a claim of negligence per se is available as a matter of Tennessee state law. *See id.* at 456 ("We must decide whether, given the nature of this case, such a state law cause of action is available to the plaintiffs.").[10]

Boston Scientific's argument also overlooks that this Court in *Martin* stated that claims that a manufacturer "did not adequately comply with the PMA *process*" were not preempted by § 360k(a). 254 F.3d at 585 (emphasis added). *Martin*'s description of the claims that were not preempted appears to encompass violations of "administrative" requirements, in Boston Scientific's parlance.

Finally, even if Boston Scientific's extra-statutory substantive/administrative distinction had any merit, it would not follow that Ms. Hughes's claims are preempted. The duty on which the claims are based—the state common-law duty

[10] Unlike the district court, Boston Scientific discusses *King* in connection with implied preemption rather than express preemption. *King* has no more to do with implied preemption under *Buckman* than with express preemption under § 360k(a).

of a manufacturer to warn of the dangers of a potentially hazardous product—is surely substantive. *Cf. Sprankle v. Bower Ammonia & Chem. Co.*, 824 F.2d 409, 412 & n.1 (5th Cir. 1987) (Mississippi failure-to-warn principles are "substantive" under *Erie R.R. v. Tompkins*, 304 U.S. 64 (1938)). Federal adverse-event reporting requirements that exist for the same purpose—alerting the FDA, the medical community, and members of the public to the potential hazards of a device—and that the manufacturer must comply with as a condition of maintaining its permission to sell the device under federal law, are no less substantive.

II. Ms. Hughes's Claims Are Not Preempted Under the *Buckman* Implied Preemption Doctrine Because They Do Not Rest on Violation of Duties Boston Scientific Owed Only to the FDA.

Departing from the district court's express preemption holding, Boston Scientific rests much of its case for preemption of Ms. Hughes's claims on the implied preemption doctrine of *Buckman*. App'ee Br. 32-41. According to Boston Scientific, *Buckman* preempts "any cause of action" involving any "failure to communicate properly with the FDA pursuant to its rules and regulations." *Id*. at 37. But *Buckman*'s holding is not nearly so broad.

Boston Scientific seeks to bolster its interpretation of *Buckman* with a sentence that it mistakenly attributes to the Supreme Court in *Buckman*: "A 'private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—

that is, when the state claim would not exist if the FDCA did not exist.' *Buckman*, 531 U.S. at 352-53." App'ee Br. 38. Contrary to Boston Scientific's citation, these words do not appear anywhere in the Supreme Court's opinion in *Buckman*. Rather, they come from the opinion of the district court in *Riley v. Cordis Corp*., 625 F. Supp. 2d 769, 777 (D. Minn. 2009), and merely reflect that court's *interpretation* of *Buckman*.[11] But the district court in *Riley*, like Boston Scientific, read *Buckman* far too broadly.

The determining factor in *Buckman* was that the lawsuit there did not invoke the breach of any duty owed to the plaintiff, but was premised solely on duties owed to the FDA—it rested entirely on what the Court repeatedly referred to as a "fraud-on-the-FDA" theory premised on the notion that the defendant had misled the agency into allowing a company to market a device. Ms. Hughes does not press any such claim in this appeal. The *Buckman* Court expressly distinguished claims, such as Ms. Hughes's, that rest on "traditional state tort law principles of the duty of care" owed by the defendant to the plaintiff. 531 U.S. at 352. And it reiterated that under *Lohr*, such claims are not preempted if they rest on state-law duties that parallel the federal requirements breached by the defendant. *Id*. That claims resting on parallel state-law duties are not preempted is what the Court meant when it said

[11] We assume that Boston Scientific's incorrect attribution of the quote was a good-faith error, but feel it necessary to correct any misimpression as to the source of those words.

that a claim could not rest "solely" on the breach of a federal requirement that involved a duty owed only to the FDA. *Id.* at 353. And while *Buckman* observed that *Lohr* did not mean that just "any violation of the FDCA will support a state-law claim," *id.*, *Buckman* nowhere held that *no* violation of federal requirements would support a state-law claim. Still less did it hold that a state is preempted from using relevant federal requirements, such as the reporting requirements at issue here, as the measure of the standard of care required of a defendant to fulfill a duty owed under traditional state tort-law principles; indeed, *Buckman* did not even address that issue.

Here, Boston Scientific does not contest that longstanding principles of Mississippi product liability law, which exist independently of federal law, require the manufacturer of a dangerous product to give reasonable warning of its hazards to consumers. The essence of Ms. Hughes's claims is that in failing to fulfill the federal-law requirements that it report serious injuries resulting from malfunctions of its device, Boston Scientific simultaneously failed to fulfill the duty it owed patients and their doctors (including Ms. Hughes and her doctor) to warn them of the dangers of the product. In that sense, although Ms. Hughes invokes the breach of the federal requirements to establish a breach of the standard of care owed to her (as well as to avoid preemption under § 360k(a) by not imposing any different or additional requirements on Boston Scientific), she does not rely "solely" on a

breach of federal law, nor does she assert the breach of a duty that would not exist but for federal law. One of the authorities cited by Boston Scientific itself, *In re Orthopedic Bone Screw Products Liability Litigation*, explains precisely how such a claim rests on duties that exist independently of the federal law whose violation is at issue:

> [C]ourts have found that violations of a federal statute or regulations constituted negligence per se under state law. But the cases make clear the doctrine of per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort.

193 F.3d at 790.

Inexplicably, Boston Scientific fails to recognize that Ms. Hughes does indeed "point[] to" breaches of "typical duties directly owed to a patient under state law." App'ee Br. 39. The duties on which she premises her claim are exactly the same types of duties that Boston Scientific acknowledges were present in *In re Medtronic, Inc., Implantable Defibrillators Litigation*, 465 F. Supp. 2d 886 (D. Minn. 2006): duties to warn patients, the medical community and the public of dangers presented by the use of the device. Just as the court in *Medtronic Defibrillators* concluded that *Buckman* did not bar a claim that a defendant's failure to report adverse events constituted a breach of state-law duties to warn, this Court should reject Boston Scientific's assertion that Ms. Hughes's claims are barred simply because she relies on Boston Scientific's violations of federal

requirements to establish its breach of parallel duties owed to her under state product liability principles.

Boston Scientific's broader reading of *Buckman*, especially when combined with its broad reading of § 360k(a), would leave virtually nothing of the Court's repeated statements in *Riegel*, *Bates*, and *Lohr* that states may provide remedies for conduct that violates federal requirements. Boston Scientific's argument is that if a state requirement does not literally track the terms of the federal requirement because it requires some reference to state tort-law principles, it is preempted under § 360k(a), but if it does literally track the federal requirements, it is barred by *Buckman* because it is not entirely independent of the federal requirements. Boston Scientific asserts that there is a narrow gap in which state remedies may remain operative, but if Ms. Hughes's claims cannot pass through that gap, it is very difficult to imagine what claims will.

Even if Boston Scientific's theory left the window cracked open for some exceedingly narrow set of claims to proceed, the theory would remain impossible to square with the principles governing federal preemption—in particular, the strong presumption against preemption of state police powers. *See Franks Inv. Co. v. Union Pac. R.R.*, 593 F.3d 404, 407 (5th Cir. 2010). The Supreme Court has recently reaffirmed the importance of the presumption in determining the scope of implied conflict preemption (on which *Buckman* is based). *See Wyeth v. Levine*,

129 S. Ct. 1187, 1194-95 (2009). Of particular relevance here, *Wyeth* stressed that courts should be especially hesitant to find preemption of claims by patients injured by unsafe medical products when those claims have not been foreclosed by an express preemption clause. *Id*. at 1196.

In *Buckman*, the Supreme Court held the presumption inapplicable because the state-law claim on its face was an attempt to enforce a duty that had no analog in traditional state common-law doctrines—the duty of candor owed by manufacturers to a federal agency. *See Buckman*, 531 U.S. at 347. But extending *Buckman* to a case such as this one, in which the claim does not seek to remedy the breach of a duty to the FDA, but looks to federal law only to give content to the manufacturer's traditional state common-law duty to warn doctors and patients of the risks of medical products, would run directly up against the presumption against preemption as articulated in *Wyeth*. Faced with a choice between taking a broad or narrow reading of *Buckman*, the presumption against preemption commands this Court to take the latter. Boston Scientific makes no effort to square its broad reading with the presumption, and, indeed, fails even to acknowledge the existence of the presumption.

III. Boston Scientific Is Not Entitled to Summary Judgment on Causation.

Unwilling to rely solely on the district court's holding that Ms. Hughes's claims are preempted, Boston Scientific asks this Court to affirm the district court

on an alternative basis not ruled on by the district court: causation. Because this issue depends on a review of the summary judgment record that the district court's disposition of the case on preemption grounds made it unnecessary for that court to perform, this Court may simply reverse the district court's ruling on preemption and remand so that the district court may consider the causation argument in the first instance. *Cf. Tunica Web Adver. v. Tunica Casino Operators Ass'n*, 496 F.3d 403, 415 n.17 (5th Cir. 2007) (allowing district court to consider on remand alternative grounds for decision that the district court did not previously reach).

Should the Court choose to reach the issue, it should reject Boston Scientific's suggestion that Ms. Hughes failed to demonstrate that there is a material issue of fact with respect to causation.[12] Although Boston Scientific devotes a large number of words to attacking the opinions and credibility of Ms. Hughes's experts, it fails adequately to come to grips with two critical points that render its arguments largely irrelevant: (1) Had the adverse incidents that Boston Scientific did not report to the FDA based on its improper "matrix" (until the FDA's intervention resulted in corrective action several years after the fact) instead

[12] Boston Scientific correctly states that the scope of appellate review of this issue is de novo in that the court of appeals applies the same standard as the district court. But Boston Scientific gives short shrift to the standard itself: whether, viewing the record in the light most favorable to the non-moving party, there is a genuine issue of material fact. *Mongrue v. Monsanto Co.*, 249 F.3d 422, 428 (5th Cir. 2001).

been reported properly and promptly, the information they revealed about the frequency of serious burns caused by the Hydro ThermAblator *would have been available to the public* without any further action by the FDA. *See* 21 C.F.R. § 803.9. Thus, Boston Scientific's argument that it is speculative whether the FDA would have conducted an investigation, required it to change the device's labels, or ordered a recall of the device if the events had been reported is beside the point. (2) Ms. Hughes's physician, Dr. Michael Weber, has given deposition testimony and submitted a sworn affidavit stating that he would not have used the device had he known of the malfunctions involving leaks and injuries that Boston Scientific failed to report, *see* R.2112-13, 2214-15, and Ms. Hughes herself likewise attested that she would not have consented to the use of the device if this information had been made available to her. R.2116-17.

To the extent Boston Scientific addresses this central evidence of causation, its principal response is that Dr. Weber's affidavit must be disregarded because it supposedly "contradicts" his deposition testimony and is "improper." App'ee Br. 46-47. Boston Scientific's argument (which is notably devoid of citation to any authority) not only ignores Ms. Hughes's testimony altogether, but also overlooks this Court's precedents concerning the circumstances in which a summary judgment affidavit may be disregarded and fails to identify a contradiction between the deposition testimony and the affidavit.

As to the law, this Court, in its influential decision in *Kennett-Murray Corp. v. Bone*, 622 F.2d 887 (5th Cir. 1980), long ago established the rule that there is nothing improper about submitting an affidavit by a witness who has also given deposition testimony, and that the affidavit cannot be disregarded, even if it is in tension or "conflict" with the deposition testimony. *Id.* at 893. Rather, "a district court should not reject the content of an affidavit even if it is at odds with statements made in an earlier deposition" unless it so directly contradicts the deposition as to justify the conclusion that it is a "sham." *Id.* at 894; *see also S.W.S. Erectors, Inc. v. Infax, Inc.*, 72 F.3d 489, 496 (5th Cir. 1996) (rejecting affidavit that contradicted deposition by offering an entirely inconsistent version of events). As the Eleventh Circuit, which also follows *Kennett-Murray*, recently put it, an affidavit must be "inherently inconsistent" with an earlier deposition to be disregarded. *Allen v. Bd. of Pub. Educ. for Bibb County*, 495 F.3d 1306, 1316-17 (11th Cir. 2007). Short of such an inherent inconsistency, arguable discrepancies between deposition testimony and affidavits present issues of credibility for the trier of fact. *See id.*; *Kennett-Murray*, 622 F.2d at 893.

Here, Boston Scientific has failed not only to identify any outright contradiction or inherent inconsistency between Dr. Weber's deposition testimony and his affidavit; it has failed to show even any tension between the two. The testimony cited by Boston Scientific on its face involves no contradiction. Dr.

Weber testified at his deposition that he was aware of the risks of leaks and burns disclosed in Boston Scientific's label for the device—that is, risks attributable to *user error*. Indeed, he also specifically testified in the deposition that he had not been made aware of a risk of leaks and burns attributable to a malfunction of the device in the absence of user error, and that he would not have used the device had he been aware of that risk. R.2112-13. Dr. Weber's affidavit, consistent with that deposition testimony, elaborated that because of Boston Scientific's failure to report them, he was not aware of the incidents of burns that were concealed by Boston Scientific's use of its reporting matrix, and that had he been aware of the risk of such burns, he would not have used the device. R.2214-15. To use *Kennett-Murray*'s terms, Dr. Weber's affidavit and deposition are not even "at odds," 622 F.2d at 894, let alone inherently inconsistent or outright contradictory.

Beyond its unfounded attack on Dr. Weber's affidavit, Boston Scientific asserts that it is merely speculative whether proper reporting of adverse events would have alerted Dr. Weber to the existence of the risk of injuries resulting from malfunctions of the device because "[t]here is no federal requirement or duty that BSC directly report such events to treating physicians." App'ee Br. 47. Boston Scientific's argument disregards that even absent such direct reports, adverse event reports are available to the medical community because the FDA makes them available to the public on-line. That availability makes them directly accessible to

treating physicians, as well as to medical researchers and journalists, who frequently make adverse reports the subject of publications and studies. *See* Bruce M. Psaty et al., *Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: Use of Cerivastatin and Risk of Rhabdomyolysis*, 292 JAMA 2622, 2625 (2004) (adverse event reports are "one source, sometimes the only source, of timely information about the adverse events associated with recently marketed drugs"); *see also* R.2159 (expert report of Dr. Kyper) (noting that authors of medical journal articles on endometrial ablation devices relied on information in the FDA's database of adverse event reports). Boston Scientific also neglects to mention its own obligation under the FDA regulations and conditions of approval of the device to update its labeling to reflect previously undisclosed risks revealed by adverse event reports. *See* R.2163 (expert report of Dr. Kyper). Thus, even without regard to such likely FDA responses as requiring relabeling, dissemination of warning letters, or recall of the device,[13] there is ample basis for finding a genuine issue of fact over whether, as Dr. Weber's affidavit stated, his failure to learn of the risks of the device was attributable to Boston Scientific's nonreporting, which kept the adverse events out of both the FDA's database and the "literature" regarding the Hydro ThermAblator. R.2214.

[13] *See* R.2164 (Dr. Kyper). Notably, Boston Scientific's "voluntary" recall of the device took place within a few months of the full reporting of events that resulted from abandonment of the reporting matrix.

CONCLUSION

For the foregoing reasons, this Court should reverse the decision of the district court and remand for further proceedings.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS OF FED. R. APP. P. 32(a) AND WITH THIS COURT'S ELECTRONIC FILING REQUIREMENTS

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,992 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and the Rules of this Court.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word 2007 in 14-point Times New Roman.

3. This brief complies with the requirements for redaction of private information; it is identical to the paper copy of the brief; and the electronic file containing it has been scanned for viruses with an updated version of a commercial virus scanning program and is free from viruses.

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