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.

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February 12, 2010

CERTIFICATE OF INTERESTED PERSONS

No. 09-60925

Jan Hughes, Plaintiff-Appellant,

v.

Boston Scientific Corporation, Defendant-Appellee.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

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REQUEST FOR ORAL ARGUMENT

Plaintiff-appellant Jan Hughes respectfully requests that the Court hear oral argument in this appeal. Oral argument would be useful to the Court because the case presents issues concerning the application of the Supreme Court's recent decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999 (2008), that have as yet received little consideration by the courts of appeals and that would benefit from the full exploration that oral argument would allow.

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JURISDICTION

Plaintiff-appellant Jan Hughes filed her original complaint in the Circuit Court of Jones County, Mississippi, on March 26, 2008. R.19.[1] On April 14, 2008, defendant-appellee Boston Scientific Corporation filed a timely notice of removal to the United States District Court for the Southern District of Mississippi under 28 U.S.C. § 1441(a). R.15. The district court had jurisdiction under 28 U.S.C. § 1332(a) based on the complete diversity of citizenship of the parties: Ms. Hughes is a citizen of Mississippi, and Boston Scientific is a citizen of Delaware, where it is incorporated, and Massachusetts, where it has its principal place of business. *See* R.1345. The action meets the amount-in-controversy requirement of § 1332(a) because Ms. Hughes's complaint seeks recovery of damages exceeding $75,000, *see* R.1346, and the action was subject to removal because Boston Scientific is not a citizen of the state in which the action was brought. 28 U.S.C. § 1441(b).

The district court entered its final judgment dismissing all of Ms. Hughes's claims on November 12, 2009. RE 17. Ms. Hughes filed a timely notice of appeal on December 14, 2009. RE 15. The thirtieth day following the entry of judgment was Saturday, December 12, 2009. Under Federal Rule of Appellate Procedure

[1] Citations in this brief to pages in the Record on Appeal take the form R.__. Citations to plaintiff-appellant's Record Excerpts take the form RE __.

26(a)(1)(C), the thirty-day period for filing a notice of appeal under Rule 4(a)(1)(A) continued to run until Monday, December 14, 2009.

STATEMENT OF ISSUES

The issues in this case are:

1. Whether the district court erred in holding that Ms. Hughes's state-law claims of failure to warn, negligence, and negligence per se, which parallel federal requirements imposed on Boston Scientific under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq*., are foreclosed by the MDA's preemption provision, 21 U.S.C. § 360k(a), which preempts state laws that impose requirements relating to the safety or effectiveness of medical devices only if they are "different from, or in addition to" requirements imposed by federal law.

2. Whether the district court erred in holding that Ms. Hughes's claims are preempted under the reasoning of *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001), which held that a purported claim of "fraud on the FDA" was contrary to federal policy but recognized that claims based on breaches of state-law duties that parallel federal law are not preempted.

STATEMENT OF THE CASE AND OF FACTS

A. Nature and Course of the Proceedings

This action is a personal injury case in which plaintiff Jan Hughes seeks to recover under principles of Mississippi tort law for injuries she suffered as the

result of the malfunctioning of a medical device, the Hydro ThermAblator, made by defendant Boston Scientific Corporation. The Hydro ThermAblator is used to treat excessive uterine bleeding, or menorrhagia, by circulating heated saline solution within the patient's uterus. *See* RE 18. In Ms. Hughes's case, the device leaked while she was undergoing treatment, causing her very serious burns. *Id.* at 21. Ms. Hughes sued Boston Scientific, raising claims that the device was defectively designed and manufactured and that Boston Scientific had provided insufficient warnings to her and her doctor of the possibility that the device would malfunction and burn the patient. *See* R.1350-55. Among Ms. Hughes's theories of recovery was that Boston Scientific was negligent per se in failing to comply with applicable federal requirements that it report incidents in which the device had malfunctioned and caused injuries. *See* R.1357-58.

Boston Scientific moved for summary judgment on the ground (as relevant here) that Ms. Hughes's state-law claims were preempted by the MDA because they sought to impose requirements on the device that were "different from, or in addition to," requirements imposed by the MDA. 21 U.S.C. § 360k(a). R.1646. Ms. Hughes responded that insofar as her claims were premised on conduct that violated federal requirements, in particular requirements that Boston Scientific report adverse incidents involving its products, they were not preempted because they paralleled, and neither added to nor differed from, federal requirements.

R.2237-70. The district court granted Boston Scientific's motion for summary judgment, finding all of Ms. Hughes's claims to be preempted and dismissing her action in its entirety. RE 18.

B. Background and Facts

1. Federal Medical Device Regulation Under the MDA.

Although the development and marketing of prescription drugs have been the subject of extensive regulation by the federal Food and Drug Administration ("FDA") since the enactment of the Food, Drug, and Cosmetic Act in 1938, medical devices, which range in complexity from elastic bandages to artificial hearts, were outside the scope of the FDA's regulatory authority until the enactment of the MDA in 1976. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-76 (1996). The MDA divided all medical devices into three categories—Classes I, II, and III—and established a tripartite scheme for their regulation. *See id.* at 476-77.

Under the MDA, Class III devices are those that treat serious medical conditions and/or pose serious risks of causing injury to patients. 21 U.S.C. § 360c(a)(1)(C).[2] Like new drugs, newly developed Class III devices that are not substantially similar to devices already on the market when the MDA was enacted must receive premarket approval ("PMA") from the FDA. *See Lohr*, 518 U.S. at

[2] Class I devices are basic items such as elastic bandages, and Class II includes such devices as hearing aids and tampons, which are more complex and have greater potential to cause harm if defective or misused.

477; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999, 1004-05 (2008). The PMA process involves a detailed review of a device's safety and efficacy, including all studies and investigations available to the manufacturer, as well as the device's proposed uses, its design, and its labeling. *See id.* at 1004. When the FDA grants PMA, its approval order conditions the manufacturer's ability to sell the device on its conformity to detailed design specifications and to the label approved by the agency. *See Riegel*, 128 S. Ct. at 1004-05. In addition, PMA is conditioned on the manufacturer's compliance with ongoing obligations under the FDA's regulations, including the requirement that the manufacturer report adverse incidents involving the device to the FDA. *See id.* at 1005. In particular, a manufacturer must report incidents in which a device "malfunctions" as well as those in which the device may have caused or contributed to a death or "serious injury." *See* 21 C.F.R. § 803.50(a); *see also id*. § 803.3 (defining "malfunction" and "serious injury"). The FDA makes such reports available to the public. *See* 21 C.F.R. § 803.9.

In contrast to new Class III devices that are subject to the PMA process, Class III devices that were already in existence when the MDA was enacted are subject to less stringent standards: Such devices, as well as devices that are their "substantial equivalents," are grandfathered, and approval to market such products may be obtained through a truncated review process generally referred to as the

"§ 510(k) process" (so named after the section as numbered in the original MDA providing for such review). *See Lohr*, 518 U.S. at 477-79. Section 510(k) review focuses on the question of substantial equivalency and does not entail a thorough examination of the device's safety and efficacy, or of its design except to the extent that it is relevant to whether it is substantially equivalent to a grandfathered device. *Riegel*, 128 S. Ct. at 1007.

The MDA, unlike the statutory provisions establishing the otherwise comparable PMA requirements for new prescription drugs, contains an express preemption provision codified at 21 U.S.C. § 360k(a). Section 360k(a) states:

> 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.

As discussed in more detail below, the Supreme Court held in *Lohr* that state tort suits involving Class III devices that receive approval through the § 510(k) process are not preempted because that process does not establish federal requirements applicable to the device. In contrast, the Supreme Court held in *Riegel* that the PMA process does establish requirements concerning the design and labeling of devices, and that state tort claims involving PMA devices are

preempted if the claims would impose liability on a device manufacturer for actions in compliance with the federal requirements. Both the *Lohr* and *Riegel* decisions agreed, however, that state-law tort claims are *not* preempted if they are based on conduct that violated federal requirements applicable to a device. *See Lohr*, 518 U.S. at 496-97; *Riegel*, 128 S. Ct. at 1011.

2. Boston Scientific's Hydro ThermAblator

The Hydro ThermAblator was developed to treat excessive uterine bleeding through means less invasive than traditional surgical treatments, such as hysterectomy. The device operates by circulating saline solution heated to 90 degrees Celsius (nearly boiling) through the uterus while a seal is maintained at the cervix to prevent the hot liquid from escaping and burning other parts of the patient's body. The hot saline is then flushed out with room-temperature saline solution, which also cools the lining of the uterus. The device is removed only after all saline solution has been withdrawn through it. Following the procedure, the endometrium, or uterine lining, is sloughed off and, if the procedure is successful, replaced with healthy tissue. *See* RE 18-20.

As a new, Class III medical device, the Hydro ThermAblator was subject to the PMA process and received approval from the FDA in 2001. R.2141. The FDA's approval order, in addition to approving the device's design and labeling, required the manufacturer to comply with specified post-approval conditions,

including the reporting of device malfunctions and of deaths and injuries attributable to the device:

> 2. ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center … within 10 days after the applicant receives or has knowledge of information concerning ... (2) Any 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.
>
> 3. REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION ... This regulation ... requires that all manufacturers and importers of medical devices ... report to the FDA whenever they receive or otherwise become aware of information from any source, that reasonably suggests that a device marketed by the manufacturer or importer: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and such device or similar device marketed by the manufacturer or importer would likely cause or contribute to a death or serious injury if the malfunction were to recur.

R.2145-46. The approval order thus incorporated FDA regulations requiring reports of deaths and serious injuries as well as malfunctions that could contribute to death or serious injury, and also *any* adverse reaction or injury that either is not addressed in the Hydro ThermAblator's labeling or is occurring with unexpected frequency. The approval order further stated that "failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of

a device that is not in compliance with these conditions is a violation of the act." R.2142.

The labeling materials for the device did not warn of the possibility of burns not attributable to user error. Rather, the device's user manual warned that burns could result from placing tubing in contact with a patient's (or operator's) body, from premature withdrawal of the device before the cooling cycle was completed, or from compromise of the cervical seal caused by a doctor's failure to maintain control of the device. *See* RE 22. Similarly, a patient pamphlet regarding the device included only a brief mention of the possibility of burns, which Boston Scientific concedes referred only to burns resulting from user error. *Id.*

Boston Scientific acquired the rights to the device in 2002, shortly after its approval. Between 2002 and 2008, Boston Scientific systematically violated its obligation to report malfunctions of the Hydro ThermAblator, including malfunctions resulting in burns to patients, in ways that significantly understated the risk of such events. Rather than complying with its obligations to report malfunctions and serious injuries, as well as *any* injuries that were not addressed by the device's labeling or were occurring with unanticipated frequency, Boston Scientific developed an "algorithm" under which it did not report burns unless they met certain criteria of its choosing. *See* RE 29-30; *see* R.2149-50, 2171. In 2008, as the result of an FDA audit of Boston Scientific's reporting compliance, Boston

Scientific stopped using its algorithm and began reporting all malfunctions resulting in burns, including injuries that occurred during the period in which it had previously used the algorithm. *See* RE 30; R.2150-51, 2171, 2173-75. The abandonment of the algorithm resulted in the reporting of over twice as many malfunctions and burns as Boston Scientific had previously reported. *See* R.2249-50, 2176-203.[3]

3. Ms. Hughes's Injuries

Ms. Hughes suffers from menorrhagia, and attempts to treat her with available medications have been unsuccessful. On October 25, 2006, Ms. Hughes underwent a hydrothermal ablation to treat her condition using Boston Scientific's Hydro ThermAblator. RE 19. It is undisputed that her treating physician, Dr. Michael Weber, used the device properly and in accordance with the instructions provided by Boston Scientific, and did nothing that could be expected to compromise the cervical seal and allow heated saline solution to escape the uterus. RE 20; *see also* R.2214.

Nonetheless, the device malfunctioned during the heating phase of the procedure, and hot liquid leaked from Ms. Hughes's cervix. *See* RE 20. Although

[3] As Boston Scientific informed the court below, during the pendency of this action, it recalled the version of the device that injured Ms. Hughes after the company submitted a supplemental PMA application and obtained FDA approval to change the design of the device to reduce the risk of leaks and resulting burns. *See* RE 42.

the device shut down and the procedure was immediately ended, Ms. Hughes suffered serious burns to both her vaginal orifice and her perineum. RE 20-21. Her injuries resulted in several weeks of treatment for burns. *Id*. In addition, because the leak required her physician to end the ablation prematurely, the procedure was unsuccessful, and Ms. Hughes's menorrhagia returned, requiring ongoing treatment with birth control pills (the same unsatisfactory medical treatment she had undergone the ablation in order to avoid continuing). *Id.* In the alternative, Ms. Hughes faces the unwelcome prospects either of another ablation—the same procedure that injured her—or a hysterectomy. *Id*.

Dr. Weber, who performed the procedure on Ms. Hughes using the Hydro ThermAblator, was not aware that a significant number of product malfunctions had caused burns to patients. Boston Scientific, on the other hand, knew about but had not reported many malfunctions, as it was required to do by the FDA's regulations and the approval order for the device. Had Dr. Weber known about the risks posed by the product, he would not have used it. *See* R.2112-13, 2214-15. Similarly, Ms. Hughes would not have consented to the treatment had she been aware of the malfunctions that Boston Scientific did not report. *See* R.2116-17.

4. The Lawsuit and the District Court's Decision

Ms. Hughes filed this lawsuit in state court seeking to recover for her injuries under Mississippi products liability law on the ground that the device that

injured her was defective as a result of a design defect, manufacturing defect, or failure to warn. After Boston Scientific removed the action to federal court, Ms. Hughes amended her complaint to add a claim of negligence per se based on Boston Scientific's failure to comply with the conditions of its PMA requiring it to report malfunctions and injuries attributable to the device. R.1357-58.[4]

Boston Scientific moved for summary judgment, principally on the ground that Ms. Hughes's claims were foreclosed by the MDA's preemption provision, 21 U.S.C. § 360k(a), which, as explained above, prohibits state laws from imposing "requirements" on devices that are "different from, or in addition to" requirements imposed under the MDA.[5] Ms. Hughes, relying principally on the Supreme Court's decisions in *Lohr* and *Riegel*, argued that her claims—in particular, her negligence per se/failure to warn claims—are not preempted by § 360k(a) because they are based on Boston Scientific's conduct that violated state-law duties that parallel requirements imposed under the MDA. *See* R.2256-64. Thus, the state-law claims she asserted did not involve requirements that were "different from, or in addition to" those of the MDA. Ms. Hughes supported her argument with a detailed

[4] Ms. Hughes also alleged that PMA for the device had been improperly obtained as a result of violations during the application process, but in this appeal she does not press that claim.

[5] Boston Scientific also sought summary judgment on state-law grounds, including that Ms. Hughes had not demonstrated a design or manufacturing defect or shown causation. The district court did not reach these arguments.

showing of the factual and legal bases of the claim that Boston Scientific had violated its reporting duties under the MDA, and that Boston Scientific's failure to report adverse events had caused her injuries because she and her doctor would not have chosen to use the Hydro ThermAblator if they had been aware of the information that the company wrongly failed to disclose. *See* R.2246-53.

The district court granted summary judgment to Boston Scientific, holding that all Ms. Hughes's claims were preempted. RE 18. The court acknowledged Ms. Hughes's showing that Boston Scientific had violated requirements that it report malfunctions and injuries involving the device, and that the deprivation of this information had resulted in her injuries because she and her doctor would not have used the device if they had been aware of the extent of the risk posed by the device. *Id*. at 28-31. Nonetheless, the court held that Ms. Hughes's claims were preempted by § 360k(a) because, in the court's view, the Supreme Court in *Riegel* "unequivocally held that state tort duties do impose requirements that are different from and in addition to the MDA requirements." RE 33.

The district court acknowledged in passing that some state tort claims might avoid preemption if they were based on conduct that violated federal requirements. The court even stated that claims of failure to warn "are not preempted if the plaintiff claims that the manufacturer failed to follow the FDA-approved process for providing the appropriate warnings." RE 34. Even so, the court held that Ms.

Hughes's claim that Boston Scientific had failed to provide an adequate warning by failing to follow the FDA process for reporting adverse events was preempted, for three principal reasons.

First, the court held that such a claim was preempted under the reasoning of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, which held that a claim of "fraud on the FDA" is impliedly preempted by the MDA. Because Ms. Hughes's claims rested on a failure to report information to the FDA, the district court concluded that they necessarily fell within the holding of *Buckman*, which in its view applied to any claim that involved anything that could be characterized as a "misrepresentation" to the FDA. RE 34-37.

Second, relying not on the relevant statutory language or the Supreme Court's decisions in *Lohr* and *Riegel* but on a decision of an intermediate Tennessee state court, the court stated that even if a claim of negligence per se based on a violation of federal standards could avoid preemption, it could do so only if the regulations violated were "substantive" rather than "administrative," and the court characterized the adverse event reporting regulations that Boston Scientific violated as merely "administrative." RE 38-39.

Finally, the district court stated that a claim of negligence per se based on a violation of FDA regulations necessarily involved the imposition of state-law requirements that were "different from, or in addition to" federal requirements

under § 360k(a), because under state-law negligence per se doctrine, not every violation of a statute or regulation gives rise to liability. In the court's view, by allowing a defendant to *escape* paying damages for some violations of a federal regulation but not others, state tort law would impose different or additional requirements on the defendant than those imposed by federal law. RE 40-41.

SUMMARY OF ARGUMENT

The district court's preemption analysis reflects a fundamental misreading of the scope of both express preemption under § 360k(a) of the MDA and implied preemption under the *Buckman* decision. To begin with, § 360k(a) by its plain terms preempts only state laws that impose requirements that are "different from, or in addition to" requirements under the MDA. In both *Lohr* and *Riegel*, the Supreme Court stressed that states may impose requirements parallel or identical to requirements imposed under the MDA, and thus that they may make conduct that violates the MDA actionable under state common law. This Court's preemption decisions under the MDA echo the Supreme Court's in this respect.

Ms. Hughes's claims that Boston Scientific's violation of reporting requirements constituted negligence per se, negligence, and failure to warn under Mississippi products liability law are exactly the kinds of claim that the Supreme Court and this Court have held is *not* preempted by § 360k(a). The state-law duties underlying these claims do not require Boston Scientific to do anything that it was

not already required to do by federal law, and thus cannot fall within § 360k(a)'s prohibition on state laws that impose requirements that add to or differ from those under federal law.

Nor are Ms. Hughes's claims impliedly preempted under the reasoning of *Buckman*. *Buckman* narrowly held that a particular type of claim—a claim of "fraud on the FDA"—premised solely on a violation of a duty to a federal agency falls outside the scope of a state's traditional power to regulate matters of health and safety. The Supreme Court concluded that such a claim is impliedly preempted because it trenches on the agency's power to police fraud against it. But *Buckman* emphasized that states may make conduct actionable when that conduct violates both a duty to the agency and a duty to the plaintiff that falls within the scope of traditional state-law regulation of matters of health and safety. Ms. Hughes's claims are not preempted under *Buckman* because they are not premised solely on a breach of a duty to the agency, but rather rise from a breach of a traditional state-law duty to her—the duty to warn of dangers of a manufacturers' products—that coincides with the reporting requirements imposed by federal law.

A broader reading of *Buckman* would not only negate the Supreme Court's repeated statements that states may make violations of federal requirements under the MDA actionable, but would also run counter to the presumption against preemption, which, as this Court has recently emphasized, strongly counsels

against both express and implied preemption of state laws that fall within the scope of the states' traditional police powers. *See Franks Inv. Co. v. Union Pac. R.R.*, __ F.3d __, 2010 WL 22337, at *2 (5th Cir. Jan. 6, 2010). Claims that a manufacturer failed to warn of the dangers of a medical device, unlike claims of "fraud on the FDA," are exactly the types of claims as to which the presumption against preemption is the strongest. Preempting such claims would far exceed the scope of congressional intent in enacting the MDA, which, as the Supreme Court has now twice held, was *not* to immunize manufacturers against claims that they injured patients by engaging in conduct that violated state-law duties and standards of care that *parallel* duties imposed by the MDA.

ARGUMENT

I. Standard of Review

This Court reviews a district court's allowance of summary judgment *de novo*, applying the "familiar standard" for summary judgment. *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F. 3d 919, 927 (5th Cir. 2006). Under that standard, summary judgment is proper only where "there is no dispute as to any issue of material fact and … the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(c)). The preemptive effect of a federal statute is, in any event, a question of law that is reviewed *de novo*. *Franks*, 2010 WL 22337, at *2.

II. Ms. Hughes's State-Law Tort Claims Are Not Preempted to the Extent That They Are Based on Conduct by Boston Scientific That Violated MDA Requirements.

A. The MDA Does Not Preempt State-Law Tort Claims That Parallel Requirements Imposed by Federal Law.

The MDA's preemption provision, § 360k(a), on its face preempts only state laws that impose requirements with respect to devices that differ from or add to requirements applicable to the same devices under the MDA. The FDA has underscored the plain language of the statute by promulgating a regulation implementing it, which provides that state laws are preempted "only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act," 21 C.F.R. § 808.1(d), and that even when such specific requirements exist, the MDA "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." *Id.* § 808.1(d)(2).

The Supreme Court has twice considered the effect of the MDA's preemption language. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, a five-member majority of the Court held that state common-law actions seeking to impose liability on device manufacturers for injuries caused by their devices were not preempted to the extent that they involved devices approved by the FDA under the § 510(k) process, because that process does not result in specific requirements

applicable to particular devices, but reflects "entirely generic concerns about device regulation generally." 518 U.S. at 501. In reaching that result, the majority in *Lohr* was "substantially informed" by the FDA regulations, cited above, that "interpre[t] the scope of § 360k's pre-emptive effect." *Id*. at 495.

Members of the Court in *Lohr* disagreed on a number of subjects, including when state common-law doctrines establish "requirements" that are subject to preemption under § 360k(a). The majority opinion suggested that most such doctrines were too general to qualify for preemption, *see id.* at 501-02, while the four dissenters would have held that tort duties establish requirements for devices within the meaning of § 360k(a). *See id.* at 509-12 (O'Connor, J., concurring in part and dissenting in part). But on one point all nine Justices in *Lohr* agreed: State-law actions that seek to enforce duties that are the same as the requirements imposed on device manufacturers under the MDA are not preempted because such actions do not impose requirements that are "different from, or in addition to" those imposed on a device by the MDA. *See id.* at 495-97 (majority opinion); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

Thus, the *Lohr* majority expressly held that a plaintiff's state common-law remedies are not barred by § 360k(a) if they are based on conduct that violates requirements imposed on the device under the MDA:

> [I]t is clear that the Lohrs' allegations may include claims that Medtronic has … violated FDA regulations. At least these claims, they suggest, can be maintained without being pre-empted by § 360k, and we agree.
>
> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.

Id. at 496. The Court emphasized that this result flowed not only from the language of the MDA itself, but also from the FDA's regulation interpreting the statute to foreclose preemption where state-law requirements are "equal to, or substantially identical to, requirements imposed by or under the [MDA]." *Id.* at 496-97 (quoting 21 C.F.R. § 808.1(d)(2)). The Court therefore found "no reason to preclude altogether" claims of manufacturing defect and failure to warn "to the extent that they rest on claims that Medtronic negligently failed to comply with duties 'equal to, or substantially identical to, requirements imposed' under federal law." *Id.*

The *Lohr* dissenters, who advocated preemption of some of the claims asserted in the case, wholly agreed on this point:

> [T]he Lohrs' claims are not preempted by § 360k to the extent that they seek damages for Medtronic's alleged violation of federal requirements. Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to," requirements under federal law.

Id. at 513 (O'Connor, J., concurring in part and dissenting in part). Thus, the *Lohr* dissenters joined the majority in voting to "reverse the judgment of the Court of

Appeals that the MDA pre-empts a *common-law claim alleging violation of federal requirements*." *Id.* at 514 (emphasis added).

The Supreme Court revisited the scope of the MDA's preemption clause in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, a case that, like this one, involved a Class III device that had undergone the full PMA process rather than the abbreviated § 510(k) review. In *Riegel*, the Court considered whether the MDA preempts tort claims that challenge the safety and effectiveness of a PMA device by asserting that its design was defective, negligent, or violated an implied warranty of fitness for use, and/or that the labeling provided inadequate warnings about the dangers and proper uses of the device. *Riegel* held that such claims are preempted because: (1) the PMA process, unlike the § 510(k) review process, establishes design and labeling requirements that are "specific to individual devices," 128 S. Ct. at 1007; (2) state tort actions premised on a theory that a device manufacturer's design or warnings for a particular device violated duties of care to a plaintiff also involve "requirements … with respect to a device" within the meaning of § 360k(a), *see id.* at 1001-10; and (3) the requirements imposed by state tort law are "different from, or in addition to" those imposed by the PMA process to the extent that state law would impose liability on a device manufacturer for a device that *complied* with the relevant federal requirements. *See id.* at 1011.

Most important for present purposes, however, the Court in *Riegel*, like both the majority and dissenters in *Lohr*, went out of its way to emphasize that a state tort lawsuit seeking to remedy injuries caused by a device is preempted by § 360k(a) *only* if it rests on a claim that the manufacturer violated a duty that goes beyond the specific requirements imposed by federal law. Claims that are based on conduct that violates *both* state law and the MDA are not preempted:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). *Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.*

Id. (emphasis added) (citing *Lohr*, 518 U.S. at 495 (majority opinion); *id*. at 513 (O'Connor, J., concurring in part and dissenting in part)).

The Supreme Court's holdings in both *Riegel* and *Lohr* that § 360k(a) does not preempt state tort claims premised on violations of parallel state and federal requirements are consistent with the Court's other recent decision construing a similar preemption provision—*Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). There, the Court considered the effect of the preemption clause of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), which, like the MDA, preempts certain state-law "requirements" that are "in addition to or different from" those imposed by FIFRA. 7 U.S.C. § 136v(b). Although recognizing that state tort actions may in some circumstances impose

"requirements," the Court held that such actions were not preempted by FIFRA to the extent that they did not impose requirements beyond those already imposed by FIFRA. The Court noted that the language of the statute would not prevent a state from imposing a sanction on a manufacturer for violating the requirements of FIFRA itself, because such a sanction would not require the manufacturer to do anything that FIFRA did not require. 544 U.S. at 442. "The imposition of state sanctions for violating state rules that merely *duplicate* federal requirements," the Court went on, "is equally consistent with the text of § 136v." *Id.* (emphasis added). Similarly, the Court held, the imposition of liability under common-law standards that are "equivalent" or "parallel" to the requirements of federal law is not preempted by FIFRA because such standards are not "in addition to or different from" federal requirements. *Id.* at 447. The Court invoked its earlier decision in *Lohr* to buttress this reading, stating that *Lohr* provided "strong support" for the conclusion that states may supply common-law remedies for persons injured as a result of the violation of federal requirements. *Id*. at 447-48. The Court noted that such state remedies "*need not* explicitly incorporate [federal] standards as an element of a cause of action in order to survive pre-emption," *id*. at 447 (emphasis added)—a statement that implies that state causes of action *may* explicitly incorporate federal requirements.

Consistent with *Lohr*, *Riegel*, and *Bates*, this Court, too, has expressly recognized that state-law tort claims premised on violations of the MDA are not preempted by § 360k(a) because the duties that such claims seek to enforce impose no requirements that are different from, or in addition to, the requirements of the federal law. In *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001), this Court anticipated the Supreme Court's holding in *Riegel* when it distinguished *Lohr* and ruled that § 360k(a) preempts certain claims against Class III devices that have received PMA. *Martin* recognized, however, that not all such claims are preempted, but only those based on state-law duties that would have the effect of imposing on device manufacturers requirements that are different from, or in addition to, the requirements imposed via the federal PMA process. By contrast,

> 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, will never contain specific requirements that are additional to or different from federal requirements. Therefore, claims based on those duties are not preempted.

Id. at 582 n.8. The *Martin* Court acknowledged that *Lohr*, by affirming state authority to provide remedies paralleling federal requirements, had implicitly overruled one aspect of this Court's prior decision in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), where the Court had taken the view that state remedies were preempted even absent a direct conflict between the standards underlying them and applicable federal standards. *See Martin*, 254 F.3d at 583.

Martin emphasized that, after *Lohr*, "tort suits based on a manufacturer's failure to follow the FDA's regulations and procedures are not preempted," and that "[i]n the context of the PMA process, we agree that state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted." *Id.*

Thus, even while holding that state-law claims challenging the FDA-approved design, manufacturing process, and labeling for the device at issue in *Martin* were preempted, the Court in *Martin* pointedly noted that the district court had denied the defendant's motion for summary judgment "on the plaintiffs' claims that Medtronic had deviated from FDA requirements." *Id.* at 575. The Court went out of its way to endorse this aspect of the district court's ruling:

> The district court specifically found those claims that paralleled the federal process—the claims that Medtronic did not adequately comply with the PMA process—were not preempted under § 360k. This finding comports with *Lohr*, that *general duties of care that parallel federal requirements are not "different from, or in addition to" federal requirements, and are therefore not preempted*.

Id. at 585 (emphasis added).

This Court returned to the question of MDA preemption in 2006 in *Gomez v. St. Jude Medical Daig Division Inc.*, 442 F.3d 919. Again anticipating the Supreme Court's decision in *Riegel*, the Court reiterated that the MDA preempts state-law claims concerning devices that have undergone the PMA process if the claims "are based on aspects of the [device's] design, manufacture, and marketing *that*

complied with the FDA-approved requirements," *id*. at 933 (emphasis added). The Court emphasized, however, that preemption analysis under the MDA must be based on consideration of "the effect a successful lawsuit asserting [state-law] causes of action would have and … whether they threaten the federal PMA process requirements." *Id.* at 929-30. Thus, "a lawsuit that simply parallels or enforces the federal regulatory requirements without 'threatening' or interfering with them is not preempted." *Id.* at 932 (citing *Lohr*, 518 U.S. at 495); *see also id.* at 930 n.2 (quoting *Martin*, 254 F.3d at 582 n. 8).

Accordingly, *Gomez* held that § 360k(a) bars claims alleging that features of a device's design and labeling that "the FDA required and approved through the PMA process were inadequate under state law." *Id*. at 931. *Gomez* similarly held that where a defendant had complied with federal requirements concerning the reporting of adverse events and updating of labels to reflect newly discovered dangers, a failure-to-warn claim was preempted. *Id*. at 931-32. But *Gomez* permitted the plaintiff to proceed with a state-law negligence per se claim that was based on violations of federal standards imposed through the PMA process (namely, a claim that the manufacturer had deviated from the FDA-approved specifications for the device in manufacturing it). *See id.* at 933. Such a claim, the Court concluded, was not "inconsistent with the federal regulatory requirements" because it did not "require[] a showing that the FDA requirements themselves were

deficient." *Id.* The Court went on to find that the plaintiff had made a sufficient case to get to a jury on her claim of negligence per se, based in substantial part on evidence that in selling the lot of devices from which the one that injured the plaintiff was taken, the manufacturer had violated FDA standards that required disposal of the entire lot based on the rate of defects in a sample tested by the manufacturer. *See id.* at 935.

Together, the Supreme Court's decisions in *Lohr*, *Riegel*, and *Bates*, as well as this Court's decisions in *Martin* and *Gomez*, establish unequivocally that the MDA's preemption provision does not preempt state-law claims that seek recovery on the basis of a breach of a state common-law duty of care that incorporates or parallels federal regulatory requirements. Indeed, the Supreme Court has twice made this point *unanimously* as to the MDA, and *Riegel* (together with *Martin* and *Gomez*) leaves no doubt that the point applies to devices that have been subject to the PMA process no less than to devices that have not. The reason, as this Court explained in *Martin*, is simple: State-law duties of care that incorporate or parallel federal standards, by definition, "will never contain specific requirements that are additional to or different from federal requirements." 254 F.3d at 582 n. 8.

B. Ms. Hughes's Claims Based on Boston Scientific's Failure to Report Adverse Incidents Are Not Preempted Because They Are Based on State-Law Duties That Parallel Federal Requirements Under the MDA.

Under Mississippi products liability law, a product is "defective" if the manufacturer has failed to provide "adequate warnings or instructions" with respect to dangers of which it knew or should have been aware. Miss. Code. Ann. §§ 11-1-63(a)(i)(2), (c)(i). Thus, Mississippi law imposes on a manufacturer of drugs or medical devices a duty to provide reasonable warnings of risks and unsafe conditions associated with their products to medical professionals who prescribe or use them in the care of patients. *See Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir. 1992); *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 691 (Miss. 1988); Miss. Code Ann. §§ 11-1-63(c)(ii). Because the adequacy of warnings turns on what is reasonable under the circumstances, claims of strict products liability for failure to warn and negligent failure to warn are, under Mississippi law, interchangeable. *See Bennett v. Madakasira*, 821 So. 2d 794, 804 (Miss. 2002) ("Although a plaintiff in a prescription drug liability case may alternatively rely on strict liability and negligence principles, 'these principles merge into one inquiry; the adequacy of the defendant's warnings.'") (quoting *Swayze v. McNeil Labs., Inc.*, 807 F.2d 464, 467 (5th Cir. 1987)).

Mississippi law concerning negligence per se further recognizes that where a defendant owes a duty of care to the plaintiff, the violation of a statutory or

regulatory requirement intended to protect a class of persons including the plaintiff is sufficient to establish a breach of the applicable standard of care, and to support imposition of liability if the breach proximately caused injuries of the type the law was intended to prevent. *See, e.g.*, *Thomas v. McDonald*, 667 So. 2d 594, 596 (Miss. 1995).[6]

Here, Ms. Hughes claims that Boston Scientific failed to provide adequate warning to her and to her physician by not reporting a significant number of adverse incidents involving burns that were not attributable to physician error—the only source of burn risk that Boston Scientific disclosed in its labeling and usage instructions—in violation of reporting requirements imposed on it by the FDA as a condition of the device's PMA. Ms. Hughes asserts that these violations of federal regulatory requirements constituted negligence per se under Mississippi tort

[6] In *Sumrall v. Mississippi Power Co.*, 693 So. 2d 359 (Miss. 1997), the Mississippi Supreme Court held that a violation of federal OSHA regulations could not be used to establish negligence per se. That result, however, rested in large part on a Mississippi statute expressly stating that OSHA standards are not incorporated into state law. *See id*. at 366 (citing Miss. Code Ann. § 71-1-1(f)). Moroever, even under the reasoning of *Sumrall*, violations of federal regulations remain admissible under a simple negligence theory to establish that the defendant's conduct was not reasonable under prevailing industry standards. *See Accu-Fab & Constr., Inc. v. Ladner*, 778 So. 2d 766, 771 (Miss. 2001) (holding OSHA standards admissible for that purpose). For preemption purposes, it does not matter whether the violation of federal regulations is used to establish lack of reasonable care under a negligence per se theory or merely as evidence that the defendant's conduct was unreasonable, as there is no preemption under § 360k(a) in either case as long as state law does not demand more of the defendant than compliance with federal requirements.

principles—that is, that the violation of the reporting requirements was a violation of the standard of care that Boston Scientific had to meet to fulfill its duty to provide reasonable warnings as well as to satisfy the express conditions of its PMA. The reporting requirements, moreover, are expressly designed to "provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device," R.2145—an objective obviously aimed at protecting patients on whom the device is used. And Ms. Hughes presented evidence that her injuries were proximately caused by Boston Scientific's violation of the reporting requirements: her doctor's testimony that if he had been aware of the incidents of burns caused by the device that Boston Scientific did not report, he would not have used the device to treat her condition, as well as her own averment that she would not have undergone the treatment had she been told of the information not reported by Boston Scientific.. R.2112-13, 2214-15, 2116-17.

The district court seemingly accepted that Ms. Hughes's claim was a proper invocation of negligence per se principles under Mississippi law, but held that the application of Mississippi tort law was preempted by § 360k(a).[7] The court's

[7] Although the district court's holding did not rest on the notion that the violation of the regulations would not constitute actionable negligence under state law, the court does not seem to have wholly understood the nature of the claim, as its opinion incorrectly suggested that the plaintiff's theory was that the failure to report was the basis of a "manufacturing defect" claim rather than claims of failure-to-warn, negligence and negligence per se. RE 36.

decision cannot be squared with the repeated recognition by the Supreme Court and this Court that § 360k(a)'s preemption of state requirements that are "different from, or in addition to" federal requirements does not extend to claims that seek to enforce state-law duties that are "equal to, or substantially identical to," or "parallel" to federal requirements. *Lohr*, 518 U.S. at 496-97. The archetype of such a non-preempted claim is one "premised on the violation of FDA regulations." *Riegel*, 128 S. Ct. at 1011.

Ms. Hughes's failure to warn/negligence/negligence per se claims fall precisely into that category. They do not seek to impose liability on Boston Scientific for anything approved by the FDA in the PMA process (such as the design or labeling of the device), and thus they neither seek a finding that anything "the FDA required and approved through the PMA process [was] inadequate under state law" nor "require[] a showing that the FDA requirements themselves were deficient." *Gomez*, 442 F.3d at 931, 933. Nor are these claims premised on the theory that Boston Scientific owed her a duty that required something *more* than compliance with the FDA's requirement that it properly report adverse incidents involving the device. Rather, Ms. Hughes claims that the exact same conduct that violated the FDA's reporting regulations violated Boston Scientific's state-law duty to warn of dangers of the device, and that that conduct—and nothing more—was the proximate cause of her injury. Because the duties and standards of care

that Ms. Hughes's claims posit demanded no more from Boston Scientific than that it do what federal law already required it to do, the claims are not preempted, as they "simply parallel[] or enforce[] the federal regulatory requirements without 'threatening' or interfering with them." *Id.* at 932.

Put another way, claims that a manufacturer failed to provide adequate warnings of the dangers of its device by failing to disclose adverse events about its device as required by federal regulations "are not preempted because, if proven, they do not impose additional or different requirements than the ones imposed by federal law." *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 2007 WL 1725289, at *8 (D. Minn. June 12, 2007); *accord In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 898 (D. Minn. 2006) ("[I]n the instance where a defendant discovers information subsequent to FDA approval which would lead a reasonable manufacturer to warn the medical community before the device is implanted into patients, a failure to warn claim is not preempted.").

This Court's treatment of the failure-to-warn claims presented in *Gomez* is instructive. The Court held them to be preempted because they demanded *more* from the defendant than compliance with the FDA's regulations concerning reporting and updating of labeling when new dangers were discovered—regulations that the defendant in that case had followed. *See* 442 F.3d at 931-32.

But *Gomez* makes clear that where a state-law claim is based on "common law duties that incorporate the PMA process," it is not preempted because "it will never contain specific requirements that are additional to or different from federal requirements." *Id*. at 930 n.2 (quoting *Martin*, 254 F.3d at 582 n.8). Thus, unlike the failure-to-warn claims in *Gomez*, a claim like Ms. Hughes's, in which the unreasonableness of the warning lies in the defendant's failure to fulfill its "ongoing obligations to report experience with the device," *id.* at 931, is not preempted by § 360k(a).

Here, the district court nonetheless concluded that Ms. Hughes's claim would impose "different" or "additional" requirements on Boston Scientific's device because a defendant in a Mississippi negligence per se action will not always be held liable whenever it violates an applicable statutory or regulatory requirement. The court explained its reasoning as follows:

> Under Mississippi law …, a violation of a law or regulation is not conclusive on the question of negligence, but is only prima facie evidence thereof. … The alleged violator is permitted to show circumstances excusing the statutory or regulatory violation and rebutting the presumption of negligence per se. … As such, common law tort principles will necessarily be imposed on BSC as it attempts to rebut a presumption of negligence. This imposes a requirement that is "different from, or in addition to" the requirements set forth in the federal regulations.

RE 41.

The district court's reasoning, drawn primarily from another district court's decision in *Bausch v. Stryker Corp.*, 2009 WL 2827954, *4 (N.D. Ill. Aug. 31, 2009), is deeply flawed. That Mississippi law may not always impose liability on a defendant who violates the federal requirements does not mean that Mississippi requires device manufacturers to report different or additional information than is required by the federal regulations or otherwise imposes different or additional requirements on manufacturers' conduct. It means only that, in some cases where federal requirements have been violated, Mississippi law may not offer a remedy to an injured plaintiff.[8] The *absence* of a remedy for some violations of federal law is not a requirement that device manufacturers do anything, let alone that they do anything different from what federal law requires.

Indeed, for this reason, the Supreme Court rejected the exact analysis employed by the district court here when it held in *Lohr* that parallel state-law claims did not impose different or additional requirements on device manufacturers even if state law would require the plaintiff to prove some additional elements in order to recover. As *Lohr* explained, features of state law that provide for recovery

[8] It is, in any event, far from clear that Mississippi law would purport to allow an excuse or justification for a violation of a federal regulation. That the state recognizes that violations of its own laws may be excused in certain circumstances by state common-law principles does not mean that the same would be true of violations of federal regulations, where any excuses or justifications for a violation would presumably be drawn from federal law.

in a *narrower* set of cases than those in which the defendant has violated federal law do not establish "additional" or "different" requirements in the sense in which those terms are used in § 360k(a):

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

Lohr, 518 U.S. at 495.

The Supreme Court reiterated this point in *Bates*. 544 U.S. at 447 n.23. And in *Riegel*, the Court cited this passage from *Lohr* with approval in reiterating that state-law claims premised on conduct that violates federal requirements are not preempted. 128 S. Ct. at 1011. The district court's determination that Ms. Hughes's state-law negligence per se claim is preempted under § 360k(a) because state tort law may impose *narrower* requirements on Boston Scientific than the FDA regulations, or may not provide a remedy in *every* case where those regulations are violated, thus cannot be squared with the Supreme Court's decisions holding that such state-law claims do not impose different or additional requirements on device manufacturers.

Citing an intermediate state appellate court decision from another jurisdiction, the district court also suggested that even if Ms. Hughes's claims are based on duties that parallel federal requirements, they are preempted under § 360k because the relevant requirements are "administrative" as opposed to "substantive." *See* RE 38-39 (citing *King v. Danek Med.., Inc.*, 37 S.W.3d 429, 457 (Tenn. Ct. App. 2000)). But § 360k(a)'s language, which is controlling, says nothing about whether requirements are "administrative" or "substantive." It provides for preemption *only* if state requirements are "different from, or in addition to" federal requirements. If the state requirements do not differ from or add to federal requirements, § 360k(a) provides no basis for holding them preempted, regardless of whether the requirements are "administrative" or "substantive." As this Court has recently observed, in express preemption cases, as in other cases of statutory interpretation, "the plain wording of the clause … necessarily contains the best evidence of Congress' pre-emptive intent." *Franks*, 2010 WL 22337 at *3 (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)). The plain language of § 360k(a) does not support importation of a wholly atextual requirement that, to avoid preemption, a requirement must be "substantive."

In any event, there is no basis for the district court's dismissal of the requirement of reporting adverse events as merely "administrative." The

requirement, as the FDA approval letter for the Hydro ThermAblator expressly states, serves a critical, substantive purpose: to "provide continued reasonable assurance of the safety and effectiveness of the device." R.2145. The importance of the requirement is underscored by the fact that a manufacturer's failure to comply invalidates its PMA and renders sale of the device a violation of federal law. Reporting of adverse events is no mere administrative chore, but is a vital mechanism to "prevent injury and death by alerting the public when potentially hazardous devices are discovered." Office of Inspector General, Department of Health & Human Services, *Adverse Event Reporting for Medical Devices*, at i (2009), http://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf. That the submission of reports is not a purely internal "administrative" requirement is also demonstrated by the regulatory requirement that reports be made available to the public, the protection of which is the ultimate goal of adverse event reporting. *See* 21 C.F.R. § 803.9.

III. Ms. Hughes's Claims Do Not Fall Within the Implied Preemption Doctrine of *Buckman Co. v. Plaintiff's Legal Committee.*

The district court erred not only in its reading of § 360k(a), but also in concluding that its preemption holding was supported by the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341. Although the district court discussed § 360k(a) and *Buckman* together, rather than as alternative theories of preemption, and even stated at one point that Ms. Hughes's

claims were "expressly preempted pursuant to … *Buckman*," RE 31, *Buckman*'s holding was based neither on § 360k(a) nor on any other theory of express preemption. Rather, *Buckman* sets forth a narrow *implied* preemption rationale applicable to claims of "fraud on the FDA." *See* 531 U.S. at 348. That rationale is inapplicable here because Ms. Hughes's did not make such a claim, and her claims do not pose the same concerns of conflict with federal policy that the *Buckman* Court saw in a "fraud-on-the-agency" claim. Indeed, Ms. Hughes's claims are wholly unlike the claim that the Supreme Court held to be impliedly preempted in *Buckman*.

In *Buckman*, the plaintiffs claimed that the defendant had violated a duty to the FDA by committing a fraud upon the agency. Specifically, the plaintiffs alleged that the defendant had misrepresented the intended use of the device so as to avoid the PMA requirement and instead obtain § 510(k) marketing permission. As the Supreme Court explained, the plaintiffs alleged that the defendant "made fraudulent representations to the Food and Drug Administration … in the course of obtaining approval to market" the product and that "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id.* at 343. The Supreme Court's opinion repeatedly emphasized that the claim before it was a "fraud-on-the-FDA" or "fraud-on-the-agency" claim. *Id*. at 347, 348, 350, 351, 352.

As described by the Court, the feature of the *Buckman* "fraud-on-the-FDA" claim that was critical to the Court's analysis was that the claim was not based on anything resembling "traditional state tort law principles of the duty of care owed by" the defendant to the *plaintiff*, *id*. at 352, but entirely on alleged duties arising from "the relationship between a federal agency and the entity it regulates." *Id*. at 347. Thus, the sole interest that the claim sought to advance was to "punish and deter fraud against the [FDA]." *Id.* at 348. That objective, the Court stressed, was one in which the states had no independent interest, and it was also one already fully served by the "federal statutory scheme[, which] amply empowers the FDA to punish and deter fraud." *Id.* Allowing state law to "[p]olic[e] fraud against federal agencies," *id*. at 347, would interfere with the federal statutory scheme by "skew[ing]" the "balance sought by the [FDA]" in enforcing prohibitions on fraud in the PMA process. *Id*. at 348. Thus, as the Court summed up its holding and reasoning, "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

Here, by contrast, the essence of Ms. Hughes's claim is not that the defendant breached a duty to the FDA, but that it breached a duty to her—namely, the duty to provide an adequate warning of the dangers of its product, which in this case paralleled its duty to comply with the conditions of its PMA. Boston

Scientific's violation of the FDA regulations requiring it to report adverse incidents involving the device serves to establish that Boston Scientific breached the applicable *standard of care* with respect to its duty to warn of dangers, not to establish (as in a preempted fraud-on-the-FDA claim) that it violated a duty to the agency for which it should be punished. *Buckman* itself stated that its preemption reasoning did not extend to actions that similarly rested on "traditional state tort law principles," *id*. at 352, and it stressed that where an alleged breach of duty did not arise "solely by virtue of [federal] disclosure requirements," *id*. at 353, a plaintiff may maintain a "state-law caus[e] of action that parallel[s] federal safety requirements," *id.*, as the Court had previously held in *Lohr*.

Although the scope of *Buckman*'s implied preemption doctrine has generated some confusion in the lower courts, the best-reasoned decisions recognize that it does not extend to claims such as Ms. Hughes's. For example, the court in *Guidant Defibrillators*, 2007 WL 1725289, rejected the application of *Buckman* to claims that a defendant's violations of FDA regulations requiring disclosure of adverse events constituted an actionable failure to warn of the dangers of a device under applicable state tort principles. The court held that *Buckman* did not bar such claims because, unlike the claims in *Buckman*, they were not premised solely on fraud on the FDA, but instead rested on the theory that the defendant's "failure to comply with various FDA regulations also violates state

statutory and common law duties." *Id.* at *10. Thus, the claims "are not based on any duty to the FDA but are instead based on alleged duties owed to" the plaintiff. *Id.*

Likewise, the same court, in *Medtronic Defibrillators*, 465 F. Supp. 2d 886, refused to apply *Buckman* to bar claims that a device manufacturer's failure to report adverse events to the FDA constituted an actionable failure to warn under state law. Pointing out that the claim in *Buckman* was "actual 'fraud-on-the FDA,' and not state tort claims involving the plaintiffs' personal injuries," the court "decline[d] to read *Buckman* so broadly" as to reach the latter. *Id.* at 899. Because the plaintiffs did "not complain of fraud on the FDA," but rather that "they, themselves, were deceived and injured" by the defendant's failure to report dangers of its device, *id*., the court found *Buckman* inapplicable to the claims. *See also Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602 (E.D. Pa. 2008) (*Buckman* limited to claims that drug or device manufacturers obtained PMA through fraud on the FDA); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018, 1039 (S.D. Ill. 2001) (*Buckman* limited to fraud-on-the-FDA claims).

Similarly, in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2007), *aff'd by an equally divided Court*, *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008), the Second Circuit held that *Buckman*'s holding was limited to cases where the plaintiff pursued a fraud-on-the-agency claim, and did not extend to "claims

that sound in traditional state tort law." *Id*. at 94. The *Desiano* court explained that traditional tort claims differ fundamentally from the claim in *Buckman* because the underlying source of the duty enforced by traditional state law is a duty owed by the defendant to the plaintiff, not a duty grounded in the relationship between a federal agency and a regulated entity. *Id*. Moreover, a state-law claim that the defendant's action in violation of federal regulations breached duties owed to the plaintiff (as opposed to duties to the FDA) differs from a fraud-on-the-agency theory in that under the latter theory "proof of fraud against the FDA is *alone sufficient* to impose liability." *Id.* In contrast, *Desiano* explained, under a traditional state-law claim, the defendant's conduct must also amount to some form of wrongdoing *toward the plaintiff*, such as marketing a defective product or failing to give adequate warning of the product's dangers. *Id.* Such claims—like Ms. Hughes's claims here—do not arise "solely" out of a violation of federal disclosure requirements and hence may be maintained under the reasoning of *Lohr* (and *Riegel*) as long as they parallel and do not add to federal requirements. *See id.* (quoting *Buckman*, 531 U.S. at 352-53).[9]

[9] *Desiano*, it should be noted, presented a more difficult case under *Buckman* than do Ms. Hughes's claims, because in *Desiano* the issue was whether an *actual showing of fraud on the FDA* could be required in litigation of a state-law claim as a means of overcoming a regulatory compliance defense. *Desiano*'s analysis of the general nature of *Buckman* preemption, however, remains persuasive even if the *Desiano* court's application of that analysis to the issue before it is an unsettled question.

Ms. Hughes's claims also differ from the *Buckman* fraud-on-the-FDA claim in another important respect: They do not require any hypothetical consideration about what regulatory action the agency would have taken if the agency had not been "defrauded." Members of the Court in *Buckman* expressed particular concern about the possibility that fraud-on-the-agency claims would require "speculation as to the FDA's behavior in a counterfactual situation" and interfere with federal policy by "second-guessing the FDA's decisionmaking." 531 U.S. at 354 (Stevens, J., concurring in the judgment). But unlike the fraud claim in *Buckman*, Ms. Hughes's claims based on Boston Scientific's violation of the *conditions* of its PMA do not rest on the theory that Boston Scientific fraudulently *obtained* PMA by concealing information from the FDA. Hence they do not require the court to explore the issue of reliance by the FDA, to reconstruct what the agency would have done if it had not been misled, or to second-guess its regulatory action or reaction in any way. As Ms. Hughes's expert pointed out in his report, action by the FDA would *not* have been necessary to prevent Ms. Hughes's injuries had Boston Scientific complied with its reporting obligations. R.2163. Ms. Hughes claims that Boston Scientific's failure to submit reports of adverse events involving its device itself caused her injury, by depriving her and her doctor of information that would have led them not to use the device. That allegation does not depend on speculation about *what the FDA would have done* if it had received the

information. It is based only on the direct effects of Boston Scientific's withholding of information not only from the FDA but also from the general public and the medical community at large, which prevented patients and practitioners such as Ms. Hughes and her doctor from learning of the device's dangers. Thus, contrary to the district court's conclusion, allowing Ms. Hughes's claims to proceed would not "usurp" the FDA's authority. RE 37.

IV. The District Court's Misconstruction of Both Section 360k(a) and the *Buckman* Implied Preemption Doctrine Improperly Expands the Reach of *Riegel* and Deprives Injured Plaintiffs of Remedies in Derogation of the Presumption Against Preemption.

The district court's reading of § 360k(a) and *Buckman* places patients injured by medical devices marketed through the PMA process in what approaches a Catch-22: On the one hand, if they plead state-law claims that rest on duties that exceed the requirements of federal law, their claims are barred by § 360k(a). On the other hand, if they assert that state law incorporates a standard of care *identical* to federal requirements, their claim is preempted by *Buckman* as an invalid attempt to premise liability solely on a breach of federal law.

Such an expansion of *Buckman* makes a mockery of the Supreme Court's repeated statements—echoed by this Court—about the limited reach of preemption under the MDA. Both in *Lohr*, which preceded *Buckman* by less than five years, and then in *Bates*, which followed *Buckman*, the Supreme Court emphasized not only that states are free to impose tort liability for conduct that violates federal law,

but that they can make the violation of federal law part of the basis for liability under state law by "explicitly incorporat[ing] federal standards as an element of a cause of action." *Bates*, 544 U.S. at 447; *see also Lohr*, 518 U.S. at 495 (claim that defendant "violated federal regulations" not preempted); *id*. at 513 (O'Connor, J., dissenting) (agreeing that MDA does not preempt "a state cause of action [that] seeks to enforce an FDCA requirement"). And in its most recent consideration of preemption under the MDA, the Court in *Riegel* reiterated that the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations." 128 S. Ct. at 1011. A claim of negligence per se, when allowed under state law, is exactly such a claim.

The Court's insistence in both *Riegel* and *Lohr* that states are not barred from providing remedies for conduct that violates the MDA has meaning only if *Buckman* is read narrowly to proscribe only state efforts to enforce duties owed solely to the FDA, such as the "fraud-on-the-FDA" claim held to be preempted in *Buckman* itself. If a state, in the exercise of its traditional function of protecting its people against defective medical products or inadequate warnings about the dangers of medical products, creates a tort remedy whose premise is that a device manufacturer owes patients a duty of care that corresponds to the requirements of the MDA, such a remedy is neither expressly nor impliedly preempted. *See*

Buckman, 531 U.S. at 353 (recognizing that *Lohr* permits such parallel tort remedies).

Ms. Hughes's claims fit comfortably within these bounds: She claims that the manufacturer's failure to comply with the federal requirements that adverse events, malfunctions, and serious injuries involving the device be reported deprived her of an adequate warning and breached conditions imposed on the device's PMA for the protection of patients. And she alleges that if Boston Scientific had provided an adequate warning and complied with the conditions on its PMA, she would not have been injured because neither she nor her doctor would have elected a procedure using the device, as both testified. Such claims avoid both the Scylla of preemption under § 360k(a) (because the state-law duties they impose on the manufacturer are identical to duties imposed by the federal requirements) and the Charybdis of *Buckman* preemption (because they do not rest solely on the manufacturer's violation of federal-law duties owed to the FDA, but on traditional state-law duties of care owed to Ms. Hughes that *correspond* to the federal duties). If this Court were to extend *Buckman* to preempt such claims, "it would place itself outside the legion of cases upholding parallel requirements to federal violations as actionable under state law." *Medtronic Defibrillators*, 465 F. Supp. 2d at 900.

Reading *Buckman* broadly to preempt Ms. Hughes's claims would not only undermine the Court's statements in *Riegel* and *Lohr* that states may offer such remedies, but would also run afoul of the presumption against preemption—the principle that the "historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." *Franks*, 2010 WL 22337 at *2 (quoting *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008)). As this Court has recently reiterated, the presumption against preemption applies both to assertions of express and implied preemption, and "operates both to prevent and to limit preemption." *Id.*

The Supreme Court likewise has repeatedly emphasized the importance of the presumption, including in its most recent decisions considering claims that personal injury actions were impliedly or expressly preempted by federal regulatory schemes: *Wyeth v. Levine*, 129 S. Ct. 1187, 1194-95 (2009) (implied preemption); *Altria*, 129 S. Ct. at 543 (express and implied preemption). As *Altria* emphasized, the presumption "applies with particular force when Congress has legislated in a field traditionally occupied by the States." 129 S. Ct. at 543. And *Wyeth* held squarely that when states provide remedies for patients injured by medical products, they are operating in just such a field—the "regulation of health and safety." 129 S. Ct. at 1195 n.3. Moreover, both *Wyeth* and *Altria* approvingly cited *Lohr*'s recognition that providing remedies for patients injured by medical

devices falls within the traditional authority of the states over matters of health and safety and thus that the presumption is fully applicable to assertions that such remedies are preempted. *See Wyeth*, 129 S. Ct. at 1194-95 (citing *Lohr*, 518 U.S. at 485); *Altria*, 129 S. Ct. at 523 (same).

Properly confined to "fraud-on-the-agency" claims or other claims that are similarly premised solely on the alleged violation of a duty owed by the defendant to a federal agency under federal law, *Buckman* does not conflict with the presumption against preemption because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." *Buckman*, 531 U.S. at 347. While *Buckman*'s reasoning forecloses application of the presumption against preemption to claims that serve only to police obligations owed to the federal government, it does not weaken the presumption as applied to "traditional state tort law" claims, *id*. at 353—that is, claims that rest on the enforcement of duties of care that a manufacturer owes users of its products. Thus, as the Supreme Court pointed out in *Wyeth*, *Buckman*'s holding that the presumption did not apply rested critically on the fact that "that case involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety as matters to which the presumption does apply." *Wyeth*, 129 S. Ct. at 1195 n.3.

Given the applicability of the presumption against preemption, this Court in construing both § 360k(a) and *Buckman* has a "duty to accept the reading disfavoring preemption." *Bates*, 544 U.S. at 449. Preemption is appropriate only if congressional intent to displace traditional state tort remedies is "clear and manifest." *Id.* (citations omitted). Neither § 360k(a), which on its face preempts only state laws that add to or differ from the requirements imposed by federal law on devices, nor *Buckman*, which calls for preemption only of actions that interfere with federal policy by imposing liability solely on account of breaches of duties owed only to the federal government, reveals a manifest congressional intent to preempt state-law claims, like Ms. Hughes's that parallel federal requirements. Indeed, far from conflicting with federal policy, such claims, as the Court observed in *Bates*, "would seem to aid, rather than hinder, the functioning" of federal law. 544 U.S. at 451.

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

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