

FDA APPROVAL OF DRUGS AND DEVICES: PREEMPTION OF STATE LAWS FOR "PARALLEL" TORT CLAIMS, 18 J. Health Care L. & Pol'y 1

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Reporter

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Text

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I. Introduction

The U.S. Supreme Court's important ruling in *Mutual Pharmaceutical Co., Inc. v. Bartlett* [1](#) concerns whether the Food and Drug Administration's ("FDA") approval of a generic drug insulates the drug manufacturer from liability under state tort laws from claims of injury due to

an alleged "design defect." [2](#) The Court previously ruled that FDA approval does not preempt state law claims based upon failure-to-warn, at least with respect to brand name

products. [3](#) In contrast, the Court previously ruled that the federal regulatory process leading to FDA approval of generic equivalents of brand drugs - and designation of the drug label - does preempt state law as to claims that challenge the warnings that accompany generic

drugs. [4](#) Thus, generic manufacturers are held immune from liability under state law for

product liability, at least as to alleged failure-to-warn of adverse effects. [5](#) This is primarily

because generic drug manufacturers have no control over the drug label, which the FDA established in consultation with [\[*2\]](#) the brand manufacturer. [6](#) In Bartlett, however, the issue was not failure-to-warn, but rather the design of the generic counterpart. [7](#) Although the active ingredients are chemically equivalent, a generic is not an identical drug. [8](#) The plaintiff in Bartlett alleged that the generic equivalent, also approved by the FDA, was flawed by a design-defect that made it unsafe for sale under state law. [9](#)

In each of these cases, the underlying issue has been whether the federal regulatory process leading to FDA approval of drugs and medical devices "preempt" state laws as to the safety issues addressed through the approval process. Thus, to summarize the applicable law prior to Bartlett, the Court had upheld failure-to-warn [10](#) claims against the brand (preemption denied) but denied failure-to-warn [11](#) claims against the generic (preemption upheld); the Court has also denied device manufacturers' liability for most product liability-related claims [12](#) (preemption upheld) pursuant to a specific statutory provision. [13](#) By a vote of 5-4, Bartlett has now denied liability of generic manufacturers on the basis of design-defect. [14](#) Following the Supreme Court opinion, however, the FDA set forth its agenda, which includes proposing a rule that would allow generic drug makers to revise their drug labels. [15](#) If created and adopted, this rule [\[*3\]](#) could again alter the landscape of liability for generic manufacturers. [16](#) Further, the related issue (which is still unresolved by the high court and is the subject of a split among the circuit courts) [17](#) is whether FDA approval of medical devices preempts all state law actions, thus insulating device manufacturers from product liability claims under all circumstances. [18](#) This Article will address each of these issues, as well as the related issue of whether off-label use of FDA-approved medical devices give rise to liability. [19](#)

II. Background

The FDA, pursuant to the Federal Food, Drug, and Cosmetic Act [20](#) ("FDCA"), is charged with the oversight of pharmaceutical and medical device production, sales, labeling, and marketing. [21](#) Pursuant to the FDCA mandate, the FDA follows a rigorous approval process for new drugs and devices that requires each product to be tested for safety and, in the case of drugs, efficacy of each intended use. [22](#) A New Drug Application ("NDA") requires the

manufacturer to submit reports of its clinical investigations, [23](#) non-clinical investigations to the extent relevant, and "any other data or information relevant to an evaluation of the safety and effectiveness of the [\[*4\]](#) drug product ... from any source." [24](#) The FDA employs a standard stating that the drugs' "probable therapeutic benefits must outweigh its risk of harm."

[25](#)

The approval process for generic drugs follow a different path. [26](#) In order to expedite the approval of generic drugs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act ("Hatch-Waxman").

[27](#) Hatch-Waxman encourages competition among generic manufacturers by allowing generic competitors to "piggyback" on FDA-approved drugs by means of an Abbreviated New

Drug Application. [28](#) A generic competitor must demonstrate that its product is the

chemical equivalent to the brand drug. [29](#) With respect to pharmaceuticals, once a product is deemed safe and effective for one or more uses, the manufacturer creates a drug label. [30](#)

The function of the drug label is to inform prescribers and consumers through the publication of the established name of the drug, its ingredients, indications, directions for use, and summary of

its adverse effects, contraindications, and effectiveness. [31](#) If the manufacturer fails to provide a complete and accurate drug label, or if the manufacturer otherwise suggests that the drug may be prescribed or recommended for other uses not approved by the FDA, it is considered "misbranding," and may subject the manufacturer to civil and criminal penalties.

[32](#) It is important to note that manufacturers of generic drugs are prohibited from altering

the drug [\[*5\]](#) label. [33](#) Indeed, approval of the generic drug can be withdrawn if the label is changed, resulting in a "misbranding" of the drug. [34](#)

The FDA's authority, which does not cover the practice of medicine, does not, however, prevent physicians from prescribing approved drugs "off label" [35](#) (which means treating conditions

not specifically approved by the FDA [36](#)). Off-label use is common and, indeed, it is

frequently even the standard of care. [37](#) As a result, the American Medical Association ("AMA") has consistently taken the position that "a physician may lawfully use an FDA-

approved drug product or medical device for an unlabeled indication" [38](#)

FDA approval of medical devices follows yet a different process. The FDCA, and specifically its Medical Device Amendments, classifies medical devices as Class I, Class II, or Class III, depending upon the potential risk or anticipated misuse or injury that may result from use of the

drugs. [39](#) Class III devices are those marketed as life-supporting devices or any other device that may cause an unreasonable risk of illness or injury, and therefore require the greatest

scrutiny. [40](#) While most Class I and II medical [\[*6\]](#) devices do not require FDA approval prior to marketing, Class III devices require substantial oversight and are subjected to a rigorous pre-marketing approval process conducted by the FDA before they may be sold. [41](#)

Despite the rigor of the FDA process, approved drugs and devices nevertheless sometimes cause injury. It is estimated that 10.2% of drugs approved by the FDA between 1975 and 1999 have either been assigned a black box warning (denoting a severe safety risk), or have been withdrawn

from the market entirely. [42](#) In some cases, it was determined that the FDA was provided

with inaccurate or incomplete data from the drug trials. [43](#) In other cases, either unanticipated side effects occurred, or known side effects occurred to an unanticipated number of

patients. [44](#) In still other cases, the efficacy was less than expected or unacceptable in light

of the risks. [45](#) Similar safety issues plague FDA-approved drugs that remain on the market, as more than 100,000 consumers are killed every year as a consequence of medical devices and

pharmaceutical use. [46](#)

The question has long been debated as to whether the federal regulatory process leading to FDA approval of drugs and devices "preempts" state law, thus foreclosing product liability actions that

challenge drug safety and/or the reasonableness of their warnings. [47](#) While the FDA can withdraw approval of a dangerous drug or device - or issue [\[*7\]](#) other mandates - the law does

not provide a private right of action to a consumer injured by an approved product. [48](#) The arguments in favor of FDA preemption are not without some appeal: the role of the FDA is to impose uniform standards for drug and medical device safety; without preemption, court decisions by individual states could undermine the FDA's regulatory framework by potentially

creating conflicting standards that intrude on the FDA's authority. [49](#) Fifty different state courts could establish conflicting standards to determine whether drugs approved by the FDA

were safe and effective. [50](#) By vesting the FDA with exclusive enforcement authority, federal law would impose uniform standards to regulate the safety and efficacy of products,

despite local rules. [51](#) Federal law also serves to discourage lay juries from making

independent determinations about safety. [52](#) Presumably, exclusive FDA jurisdiction would also prevent litigants from bringing legal action based on claims that a certain product should not have gained FDA approval at all. [53](#)

Of course, opponents of preemption also have a compelling argument: the FDCA does not include any private right of action. [54](#) In the absence of state tort laws, there would be no redress for plaintiffs who sustain severe injuries from unsafe pharmaceutical products. [55](#) In 2009, the U.S. Supreme Court, after considerable oral argument and review of the legislative history of the FDCA, determined that such a result was unacceptable. [56](#)

[\[*8\]](#) Addressing the issue of brand liability, the Court issued a landmark opinion in the 2009 matter of *Wyeth v. Levine*. [57](#) In *Levine*, a Vermont woman brought a personal injury claim in state court after injecting the drug Phenergan. [58](#) The drug was manufactured by Wyeth Laboratories and is an antihistamine, which prevents against nausea. [59](#) Complications arose from the injection, which eventually led to the amputation of Ms. Levine's arm. [60](#) The plaintiff alleged that Wyeth had failed to include in its label a description of the potential arterial injuries that could result from a negligent injection of the drug. [61](#) Wyeth defended on the basis that its label included FDA-required and approved warnings, and that such FDA approval preempted state law tort claims for failure-to-warn. [62](#)

The *Levine* jury awarded damages after finding the label, despite approval by the FDA, to be insufficient under local tort law. [63](#) The Supreme Court of Vermont affirmed, concluding that FDA requirements "merely provide a floor, not a ceiling" for state regulation. [64](#) Thus, states are entitled to require more stringent measures for labeling drugs as long as they are not inconsistent with the FDA requirements. [65](#) The U.S. Supreme Court also affirmed, finding that state-law tort actions for failure-to-warn against a manufacturer of a brand drug are not preempted by the FDA approval process. [66](#)

Wyeth v. Levine stands in sharp contrast to the U.S. Supreme Court's 2011 decision in *PLIVA, Inc. v. Mensing* ("PLIVA"). [67](#) There, the Court [\[*9\]](#) was confronted with an alleged "failure to warn" claim where the plaintiff sued a generic drug manufacturer under state law for

inadequately labeling its generic product. [68](#) The plaintiff in PLIVA alleged that she developed the (often irreversible) movement disorder, known as tardive dyskinesia, [69](#) as a result of taking PLIVA's metoclopramide (the generic form of Reglan) - a drug used to treat a digestive tract problem. [70](#) The plaintiff brought a state law failure-to-warn claim against the generic manufacturer, alleging that the warnings accompanying the drug failed to adequately warn consumers that prolonged use of metoclopramide could cause tardive dyskinesia. [71](#)

The case ultimately reached the U.S. Supreme Court, which denied the plaintiff's claim in a 5-4 ruling. [72](#) The Court held that the FDA requirement that generic drugs be chemically equivalent to the brand product also prevents generic manufacturers from altering the FDA-approved label. [73](#) Thus, the PLIVA Court found that with respect to generic drugs, FDA regulations preempt state law and preclude failure-to-warn claims. [74](#) To hold otherwise would require generic manufacturers to do the impossible: comply with FDA labeling requirements, while also complying with various state laws by altering the label to impose stricter warnings in order to avoid allegations of failure-to-warn. [75](#)

Levine also stands in contrast to the U.S. Supreme Court's 2008 opinion in Riegel v. Medtronic, Inc., [76](#) a case that concerns whether FDA approval of medical devices insulates the manufacturer from state law product liability. [77](#) In Riegel, the plaintiffs represented a class in an action against the manufacturer of a balloon catheter, which allegedly ruptured while in the lead plaintiff's artery during the course of an angioplasty [\[*10\]](#) procedure. [78](#) The manufacturer of the balloon catheter had sought pre-marketing approval of the device by the FDA. [79](#) The FDA's protocol for approval of medical devices requires increasing scrutiny, depending upon the classification of the device. [80](#) The catheter at issue was a Class III medical device that required the highest level of FDA participation: pre-marketing approval.

[81](#) The federal district court granted summary judgment to the defendant on the basis that pre-marketing approval had been granted, [82](#) and the Second Circuit Court of Appeals thereafter affirmed. [83](#)

After granting certiorari, the U.S. Supreme Court found that, with respect to devices, the FDCA - specifically including its Medical Device Amendments ("MDA") [84](#) - operates as the

exclusive enforcement mechanism to establish the safety of medical devices approved, pursuant to the FDA's rigorous regulations guiding Class III devices. [85](#) The MDA's exclusivity provision that is applicable to medical devices (but not drugs) expressly "preempts" state laws, and a plaintiff injured by a medical device cannot look to state courts for compensation that would otherwise be available under tort theories such as negligence, failure-to-warn, or breach of warranty. [86](#)

Although it might appear that the issue in the 2013 *Mutual Pharmaceutical Co., Inc. v. Bartlett* [87](#) case concerning the tort liability of a generic manufacturer would have been resolved by *PLIVA*, *Bartlett* presented the Court with an alternative theory of product liability. [88](#) The plaintiff in *Bartlett* alleged that the drug should not have been marketed, [\[*11\]](#) despite FDA approval. [89](#) The plaintiff's arguments rested not on the basis of failure-to-warn, but on marketing a drug that the plaintiff claimed was unreasonably dangerous due to an alleged design-defect. [90](#) Neither *PLIVA* nor *Levine* had previously considered the state law tort liability of a generic manufacturer on the basis of design-defect. [91](#)

Before reviewing the *Bartlett* decision, as well as the pending cases on the related issue of medical device liability, it is important to define two forms of preemption that the courts distinguish: express preemption, and implied preemption. Express preemption occurs when a statute or case law explicitly provides for it. [92](#) The MDA, for example, contains a specific (statutory) provision concerning the exclusivity of the MDA and Congress's (arguably) stated intent that they occupy the field to the exclusion of conflicting state laws. [93](#) So-called "implied preemption" occurs not from an explicit statutory pronouncement, but by implication when another federal statute or regulation occupies the field in such a way that its intended effect cannot be carried out if a conflicting state law is enforced. [94](#) In this context, it is alleged that the process for FDA approval of drugs implicitly preempts certain kinds of claims that give rise to state tort actions. [95](#) Specifically, those cases where a plaintiff alleges that a manufacturer made an incomplete or fraudulent representation to the FDA that led to its product's approval, and the product thereafter resulted in harm to the plaintiff (which constitutes a so-called "fraud on the FDA" claim). [96](#) The rationale is that the FDA regulatory process "occupies the field" on this [\[*12\]](#) issue, and that such claims should remain within the exclusive enforcement authority of the FDA: [97](#)

the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law. [98](#)

The concept of "implied preemption" thus addresses the concern that the FDA might determine that certain mandated disclosures were complete or adequate, only to have lay juries in state

courts second-guess such disclosures and find them insufficient under local law. [99](#) In an undertaking where FDA approval is the gold standard, the argument is that manufacturers should not be held to satisfy the standards of the FDA's regulatory regime while also complying with

every state's individual tort laws; [100](#) if manufacturers are brought to state court, then manufacturers would be subject to the unpredictability of countless jury verdicts rendered under

a spectrum of different standards. [101](#) This argument has largely been successful with respect to medical devices governed by the MDA, while it has largely been unsuccessful with respect to state law negligence and failure-to-warn claims as to FDA-approved brand drugs

where there is no analogous statute to provide immunity. [102](#)

[\[*13\]](#)

III. Mutual Pharmaceutical Co., Inc. v. Bartlett

A. First Circuit Opinion

In Mutual Pharmaceutical Co., Inc. v. Bartlett, [103](#) the plaintiff suffered pain in her shoulder, and to treat this pain, she was prescribed a generic form of the non-steroidal anti-

inflammatory drug ("NSAID") known as Sulindac. [104](#) NSAIDs are known to cause two rare but serious hypersensitivity skin reactions that include necrosis of the skin and mucous

membranes (toxic epidermal necrolysis), [105](#) and a somewhat less severe related condition,

Stevens-Johnson Syndrome. [106](#) When the Sulindac was prescribed to Ms. Bartlett in 2004, the label did warn of "severe skin reactions," but did not specifically identify either toxic

epidermal necrolysis or Stevens-Johnson Syndrome as a potential risk. [107](#) Both conditions, however, were listed on the package insert as potential adverse reactions, as was the possibility

of death. [108](#)

The First Circuit noted that the trial court found "overwhelming evidence" that Sulindac caused Ms. Bartlett to suffer Stevens-Johnson Syndrome/toxic epidermal necrosis ("SJS/TEN"), and that

as a result, she was left permanently injured and horribly disfigured. [109](#) Bartlett's lawsuit alleged that Sulindac had a defective design, and urged the court to find that Sulindac was unreasonably dangerous under the product liability standards [\[*14\]](#) that were in effect in

Bartlett's home state of New Hampshire. [110](#) Mutual defended on the basis that claims of design-defect are preempted under federal law since the FDA requires the active ingredients in

generic drugs to be chemically equivalent to those in the brand. [111](#) A jury found in favor of

the plaintiff and awarded her \$ 21.06 million dollars in compensatory damages. [112](#) The First Circuit Court of Appeals affirmed the jury verdict, and Mutual appealed to the U.S.

Supreme Court. [113](#)

In pursuing her theory of a state-law design-defect on appeal to the First Circuit, Bartlett alleged that Sulindac's "risks outweighed its benefits[,] making it unreasonably dangerous to consumers, despite the [FDA] having never withdrawn its statutory "safe and effective" designation that the original manufacturer had secured[,] and on which Mutual was entitled to piggyback." [114](#)

Mutual's appeal alleged that federal law forbids the generic drug from altering the label. [115](#) The First Circuit acknowledged this basic PLIVA principle, but distinguished its finding on the basis that Bartlett purported that the drug had a design-defect that made it "unreasonably

dangerous" under New Hampshire law. [116](#) Thus, the First Circuit was not critical of the fact that the label did not warn the plaintiff of her injury; rather, the First Circuit concluded that the generic manufacturer [\[*15\]](#) had not foreseen the inherent danger of such injuries and opted

not to market the product at all. [117](#)

The First Circuit's opinion in Bartlett represented a departure from a binding line of cases to the contrary, and Bartlett's holding would require that generic manufacturers be liable for injuries

caused by a product that the FDA did not deem to be unreasonably dangerous. [118](#) The Solicitor General argued in his amicus curiae brief that the obligation to determine the risk, benefit, and overall safety of drugs was within the exclusive purview of the FDA, and that neither generic nor brand manufacturers should make decisions about whether drugs were too

risky for marketing. [119](#) The Solicitor General urged the Court not to impose a duty on a manufacturer to recall a drug, either brand or generic, when it is deemed to have a design-defect.

[120](#) To do so otherwise, he argued, would interfere directly with the authority of the FDA as final arbiter of the safety and effectiveness of approved drugs. [121](#)

The First Circuit also reviewed *Wyeth v. Levine*, [122](#) where the U.S. Supreme Court found that state-law tort actions for failure-to-warn against a manufacturer of a brand drug are not

preempted by the FDA approval process. [123](#) Of course, neither *Wyeth* nor *PLIVA* addressed the issue of whether consumers can bring claims alleging design-defect against drug

[\[*16\]](#) manufacturers. [124](#) These cases are significant, however, in that the Supreme Court clearly treated brand and generic drugs differently with respect to product-liability claims based

upon failure-to-warn. [125](#) In its 5-4 holding, the *PLIVA* Court concluded that generic drug manufacturers would be shielded from liability on the basis that they cannot alter the drug label.

[126](#)

It is notable that the First Circuit in *Bartlett* relied primarily on the Supreme Court's opinion in

Wyeth, while the First Circuit largely sidestepped the decision in *PLIVA*. [127](#) *Bartlett* noted that although *Wyeth* is "technically limited to failure-to-warn claims, its logic applies to design

defect claims as well." [128](#) Indeed, it opined that *PLIVA* "carved out an exception to *Wyeth*, finding that the *FDCA* preempts failure-to-warn claims against generic drug

manufacturers... [because] the generic maker cannot alter the labeling" [129](#) According

to the First Circuit, *Wyeth* established "a general no-preemption rule," [130](#) and that if a generic drug company places a drug on the market, it incurs the potential for state law failure-to-

warn and design-defect claims. [131](#)

Bartlett challenges the heart of the preemption issue: *PLIVA* and *Wyeth* were concerned that 50 different states would impose duties on a manufacturer, duties of which would be considered to

be in addition to those duties imposed by the federal government. [132](#) The appellate court in *Bartlett* specifically commented: "it is up to the Supreme Court to decide whether *PLIVA*'s exception is to be enlarged to include design-defect claims. Given the widespread use of generic drugs and the developing split in the lower courts, this issue needs a decisive answer from the

only court [\[*17\]](#) that can supply it." [133](#) Ms. *Bartlett*'s severe injuries provided a

compelling example of the damage that can be caused by adverse side effects. [134](#)

B. U.S. Supreme Court Opinion

1. The majority opinion

On June 24, 2013, the U.S. Supreme Court, by a vote of 5-4, found that state-law damage claims against a generic drug company alleging that design-defects (which are rooted in the inadequacy

of the accompanying warnings) are preempted by federal law. [135](#) Noting that New Hampshire's tort law requires drug manufacturers to ensure their drugs are not unreasonably unsafe, the Court concluded that drug safety must be evaluated on the basis of the chemical

formulation and the content of the warnings. [136](#) Relying upon its own recent decision in *PLIVA, Inc. v. Mensing*, where the Court found that FDA regulations prohibit a generic manufacturer from altering either the drugs' composition or label, the Court here concluded that the Supremacy Clause renders the New Hampshire law "without effect," and is effectively

preempted since it would require a party to violate federal law. [137](#)

For purposes of analysis, Justice [Alito](#), writing for the majority and reversing the decision of the First Circuit, concluded that a solution that only gives drug manufacturers the option to remove a

product from the market or pay for injuries is tantamount to "no solution" at all: [138](#) "under the Supremacy Clause, from which our pre-emption doctrine is derived, any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law,

must yield." [139](#) The majority went on to conclude that even if there were no express preemption, New Hampshire law would be impliedly preempted because it is "impossible for

[\[*18\]](#) a private party to comply with both state and federal requirements." [140](#) Of particular significance is the fact that the Court disavows any obligation to inquire into congressional intent as to whether preemption was a desired consequence of the regulations.

[141](#) Both Justice Breyer and Justice [Sotomayor](#), who authored separate dissenting opinions, substantially relied upon evidence that the majority's conclusion was not consistent with FDA

policy, despite the FDA's position as articulated in its amicus curiae brief. [142](#)

The majority relied heavily on the language of New Hampshire's tort law. [143](#) New Hampshire requires manufacturers to ensure that their products are not unreasonably dangerous.

[144](#) According to the majority, this can be accomplished either by modifying the product design, or by adapting the warning label. [145](#) To assess whether a product is unreasonably dangerous, New Hampshire imposes a "'risk-utility approach' under which 'a product is defective as designed if the magnitude of the danger outweighs the utility of the product.'"

[146](#) In conducting that balancing test, New Hampshire examines three factors: (1) the desirability and usefulness of the product; (2) the ability of the manufacturer to reduce the risk without materially affecting the desirability and usefulness of the product (including the cost); and (3) the strength of the warnings to highlight hidden dangers from uses that can be foreseen.

[147](#) Since redesign of Sulindac was not an option in [\[*19\]](#) Bartlett, the lower court's inquiry focused on the ineffectiveness of warnings as evidence of a design-defect. [148](#)

The trial court in Bartlett had devoted considerable attention to Sulindac's label, even allowing into evidence a Comprehensive Review of NSAIDs that was completed by the FDA in 2005 (after the Plaintiff's injury), as well as the FDA's recommendation for a change of the label.

[149](#) The change specifically included identifying toxic epidermal necrolysis as a possible adverse effect of both brand and generic NSAIDs. [150](#) Indeed, a specific jury instruction directed deliberations in which the jury would evaluate the drug label to assess whether it was

unreasonably dangerous. [151](#) The court pointedly instructed the jury that it "should find 'a defect in design' only if it found that 'Sulindac was unreasonably dangerous and that a warning

was not present and effective to avoid that unreasonable danger.'" [152](#) The trial court, finding in favor of the plaintiff, based its ruling on the jury's determination that an inadequate

label made the product unreasonably dangerous pursuant to New Hampshire law. [153](#) Since it was clear to the majority that the jury verdict of "design defect" was directly premised upon a finding of an inadequate warning, the Court found that the case would fall clearly within the

PLIVA, Inc. v. Mensing doctrine. [154](#)

Summarizing its preemption rationale, the Bartlett majority concluded that when, as here,

"federal law forbids an action that state law requires, the state law is "without effect.'" [155](#)

This is what the majority identified as "impossibility pre-emption." [156](#) With respect to Bartlett's contention that Mutual could decline to market Sulindac or pay damages, the majority was unreceptive, rejecting out of hand what it called the "stop-selling rationale" as incompatible

with principles of preemption. [157](#) The majority refused to construe the law as to hold that a party had a viable option to either cease its [\[*20\]](#) operation or accept liability: "Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be

"all but meaningless.'" [158](#) Presumably, the Court rejected the solution suggested in the dissenting opinions because it would relegate a generic manufacturer to the status of a sitting duck, vulnerable to suits from any injured party and without recourse or ability to defend itself.

The majority and the dissenting opinions found agreement on a single point that may be significant to the future of preemption jurisprudence: Ms. Bartlett's injuries were tragic and devastating, and all opinions would welcome, if not urge, Congress to resolve this preemption

issue that has "vexed the Court - and produced widely divergent views." [159](#) Because the

FDCA "includes neither an express pre-emption clause (as in the vaccine context) (citations omitted) nor an express non-pre-emption clause (as in the over-the-counter drug context)

(citation omitted) ... [the Court] is left to divine Congress' will ... " [160](#) and resort to interpretations of statutory and common law, about which there is fundamental disagreement.

[161](#)

2. The Breyer dissent

Justice Breyer, joined by Justice Kagan, issued a brief but compelling dissent. Justice Breyer criticized the majority's conclusion that it was "impossible" to comply with both New Hampshire

and federal law, which the majority found to be hopelessly in conflict. [162](#) In Justice Breyer's view, Mutual had two options, consistent with state and federal law: (1) it could refuse

to do business in New Hampshire, [163](#) or (2) it could incur damages under New Hampshire

law that result from injuries to consumers. [164](#)

[\[*21\]](#) Justice Breyer acknowledged that there was a divergence of opinion on the preemption issue, but in his view, "where the Statute contains no clear pre-emption command, courts may infer that the administrative agency has a degree of leeway to determine the extent to which

governing statutes, rules, [and] regulations ... have pre-emptive effect." [165](#) Justice Breyer pointed out that although the FDA contributed an amicus curiae brief on the case, in developing its position, the FDA neither held hearings nor solicited opinions and arguments from the public.

[166](#) The FDA also did not issue regulations - which it could have done. [167](#) Quoting

Bowen v. Georgetown Univ. Hospital, [168](#) Justice Breyer commented that an "'agency litigating positions that are wholly unsupported by regulations, rulings, or administrative

practice' are entitled to less than ordinary weight." [169](#) Justice Breyer also noted that, unlike *Medtronic, Inc. v. Lohr*, where preemption is addressed by statute, the FDCA contains no

analogous general preemption provision with respect to drugs. [170](#) Indeed, Justice Breyer noted that in other contexts, the FDA has welcomed state tort law as a kind of "complementary

form of drug regulation." [171](#)

3. The Sotomayor dissent

Justice [Sotomayor](#), with whom Justice Ginsburg joined, issued a separate and blistering dissent.

[172](#) For purposes of analysis, Justice [Sotomayor](#)'s dissent divided the operative (preemption) provision into two major constituent parts: (a) the intent of Congress on the issue of

preemption as gleaned from other FDA contexts; [173](#) and (b) the debate over the so-called "impossibility" preemption, specifically in contrast to her description of "obstacle" preemption.

[174](#)

On the issue of congressional intent, Justice [Sotomayor](#) initially notes the "conspicuous" absence of *Wyeth v. Levine* [175](#) from the majority opinion, [\[*22\]](#) even though *Levine* is clearly distinguishable on the basis of brand vs. generic liability. [176](#) Justice [Sotomayor](#) also points out that matters of health and safety, traditionally subject to a state's police powers, should not be "superseded by a Federal Act unless that was the clear and manifest purpose of Congress."

[177](#)

According to Justice [Sotomayor](#), *Levine* supports the principle that "federal drug law and state common-law liability have long been understood to operate in tandem to promote consumer safety." [178](#) *Levine* acknowledged that even "as Congress 'enlarged the FDA powers,' it also 'took care to preserve state law.'" [179](#) More specifically, "Congress adopted a savings clause providing that the amendments should not be construed to invalidate any provision of State Law absent 'a direct and positive conflict.'" [180](#) Finally, Justice [Sotomayor](#) emphasizes that the FDCA does not contain any provision that would evince intent to preempt the FDA regulations (brand or generic); [181](#) indeed, if the FDA intended preemption, it would have said so - just as it did with respect to medical devices. [182](#) Concluding her opinion with legislative history, Justice [Sotomayor](#) offered that the absence of a federal damages provision in the FDCA may, in fact, reflect Congress's expectation that state tort law would provide for monetary compensation to injured plaintiffs. [183](#)

Turning to the issue of preemption on the basis of impossibility, Justice [Sotomayor](#) would require *Mutual* to demonstrate an "irreconcilable conflict" concerning the state and federal

provisions before concluding there was a conflict. [184](#) When there is a genuine conflict, according to Justice [Sotomayor](#), the inquiry into congressional intent is unnecessary, as the

language of the statute would make the conclusion of preemption "inescapable." [185](#) Justice [Sotomayor](#) thus rejects the majority's [\[*23\]](#) "impossibility" argument, suggesting that a clear option in *Bartlett* was to simply compensate the small number of consumers who are injured.

[186](#)

Citing, as a starting point, a "presumption against pre-emption," Justice [Sotomayor](#) introduces the alternative concept of "obstacle pre-emption," which is not explained or defended by the majority. [187](#) As Justice [Sotomayor](#) describes, obstacle preemption applies when the state law ""stands as an obstacle to the accomplishment of federal objectives." [188](#) Here, the FDA's policy was to approve Sulindac to be used for its intended purpose. [189](#) It was not to prevent consumers injured by the drug from receiving fair compensation. [190](#) Pursuant to this obstacle preemption rationale, state law would be preempted only if state failure-to-warn or design-defect statutes "stands as an obstacle to" making Sulindac available for consumer use.

[191](#) Justice [Sotomayor](#) concludes by acknowledging that Mutual's obstacle preemption defense presents a closer question, but that it would also fail, as it conflicts with "the purposes and objectives of the FDCA, as supplemented by the Hatch-Waxman Act." [192](#)

Justice [Sotomayor](#) seemed to acknowledge that her position would be at least partially at odds with the Court's 2011 decision in *PLIVA, Inc. v. Mensing*, [193](#) which she refers to as an "outlier." [194](#) There, the Court found that there was "impossibility" preemption on the basis that a generic manufacturer could not offer product warnings that would conform to Minnesota's duty-to-warn without altering the FDA-approved drug label. In Justice [Sotomayor](#)'s view, however, even *PLIVA* does not pre-ordain the Bartlett majority's conclusion for the same reasons: the defendant could choose either not to market the product, or to compensate injured plaintiffs. [195](#)

[*24] Returning to her policy rationale, Justice [Sotomayor](#) concludes her dissent by pointing out that Congress has not only spoken to the issue of state law preemption in other contexts, but that Congress has also responded "when it believes state tort law may compromise significant federal objectives." [196](#) Justice [Sotomayor](#) points to state vaccination laws, also subject to pre-market approval, to illustrate her point. [197](#) Pursuant to early FDA vaccination policy, once the FDA approves the vaccine, compensation for vaccine-induced injuries was left to the states.

[198](#) In 1986, Congress was concerned about an increase in state law tort litigation, and thus responded by enacting a National Childhood Vaccine Injury Act. [199](#) Among Congress's provisions was a hallmark no-fault compensation scheme to compensate victims of vaccine-related injuries or death. [200](#) According to Justice [Sotomayor](#), Congress has thus demonstrated the willingness and ability to act when it believes that state tort law operates to the detriment of federal objectives. [201](#) By imposing preemption in Bartlett without

congressional action, the Court leaves the intent of Congress unspoken, and leaves injured consumers without recourse. [202](#)

C. Analysis of Bartlett in Light of PLIVA

In this split decision, the 5-justice majority extended the logic of PLIVA to claims of design-defect. [203](#) In PLIVA, the Court had previously found that failure-to-warn "defects" were preempted by the FDCA because of the FDCA's prohibition on behalf of the generic in changing the brand's label. [204](#) The design of the label is part of the design of the drug, and the failure-to-warn is a failure of the label, which is a flaw of the drug itself. [205](#) [\[*25\]](#) Thus, the majority did not note a viable distinction between a label's failure-to-warn and a design-defect based upon the failed label.

Justice [Sotomayor](#)'s dissent, while thoughtful, requires that PLIVA be repudiated. [206](#) There is no logic that would allow PLIVA to stand and for Bartlett to fail, and her sympathy for the case at hand doesn't fix the gap in logic. It is doubtless why Justice Breyer declined to join, instead deciding to issue his own dissent that was short and pragmatic. Just because the FDA approved a product doesn't end the inquiry; if the product was flawed (by design or by label) and a manufacturer chose to market it anyway, the manufacturer should be liable for damages.

[207](#)

In many respects, the "impossibility" defense is at the heart of both PLIVA and Bartlett. It was "impossible" for the generic manufacturer to change the drug's label. [208](#) Failure to adjust the label to meet state law (New Hampshire, for Bartlett) was a violation of state tort principles.

[209](#) Ergo, there is a conflict between state and federal law, and the Supremacy Clause dictates that federal law preempts the incompatible state law. [210](#) The fact that the generic might have gone back to the FDA and requested a stronger label, or the fact that a stronger label specifically identifying the type of injury suffered by Ms. Bartlett was later approved is legally without consequence; at the time of injury, neither had actually occurred. [211](#)

Having dismissed the idea that liability could be found on the basis of an ill-designed label, either directly or indirectly, the only remaining option for the Bartlett and PLIVA defendants would be to make a business judgment: what is the expected (liability) cost of marketing the product as is, and can the manufacturer charge a reasonable price in view of the expected liability? The majority rejected this "stop selling" option as "all but meaningless" for both

PLIVA and Bartlett, concluding that if [\[*26\]](#) impossibility preemption were to have any meaning at all, it would not be to simply tell victims that there is no recourse in the law. [212](#)

The Breyer dissent, rather than attempting to distinguish PLIVA, [213](#) quotes two former FDA commissioners, who stated that "the FDA has long believed that state tort litigation can "supplement the agency's regulatory and enforcement activities"" in support of Justice Breyer's

conclusion that paying damages in the nature of strict liability is a viable option. [214](#) The majority and two dissenting opinions seem to agree that discerning the intent of Congress is key,

[215](#) but disagree on what Congress would conclude. [216](#) All agree that *Wyeth v. Levine* reflects congressional intent that FDA regulation should be supplemented with state tort

law, both as a check on the federal approval process and as a means of compensation. [217](#)

The Breyer dissent would extend the logic to generics: "Tort suits can help fill the gaps in federal

regulation by "serving as a catalyst" to identify previously unknown dangers." [218](#) The majority, however, noting the critical distinction between brand-name drugs and generics, denies

that Congress intended for the logic of *Levine* to extend to generic counterparts. [219](#) The majority concludes that the jurisprudence of impossibility, coupled with absence of congressional activity following PLIVA, evinces the intent of Congress that brand and generics

be treated [\[*27\]](#) differently. [220](#) It may be on this point that Justices Breyer and Kagan, also dissenting, declined to join *Sotomayor*, as it is impossible to reconcile the logic of a different conclusion with PLIVA.

It is not unusual for the FDA to approve a generic drug, only to discover latent safety issues after

it has been on the market. [221](#) Despite the FDA's official position as articulated in its amicus curiae brief, former FDA commissioners Donald Kennedy and David Kessler support the imposition of state tort liability as a means of supplementing FDA efforts to ferret out unsafe

products. [222](#) Kennedy and Kessler cite the agency's lack of adequate resources to

effectively police the drug market, which is part of the FDA's core mission. [223](#) Opponents speculate that some state tort laws would render the marketing of generics prohibitively expensive, which would be complicated by complex distribution systems that make it difficult to

sell in some states but not others. [224](#) It is doubtless that FDA preemption of state tort claims affects cost, and a change in the law would presumably result in a price increase for

generic products. [225](#)

D. The FDA Proposes New Labeling Requirements

Just days after the Court's decision in *Bartlett*, the FDA released its most recent government agenda that includes new rules under consideration by various government agencies. [226](#) Included in that agenda was the FDA's intent to raise the issue of a revision to its labeling

requirements for generic drug makers. [227](#) The FDA intends to publish a proposed rule that allows generic drug makers to make changes to product labels, independent of a brand-name manufacturer. This rule would empower generic companies to [\[*28\]](#) notify consumers about safety risks and concerns they become aware of, supporters say. In turn, it could potentially make generic drug makers liable in court for failing to do so. [228](#)

If, in fact, the FDA does consider and issue new rules revising its labeling requirements, such rules would be at odds with the position of the United States as *amicus curiae*, which supports Mutual's position against FDA preemption:

The Court need not decide whether the FDCA would preempt a "pure" design-defect claim that does not consider the adequacy of labeling. That issue is difficult and close, with several factors weighing in favor of finding no preemption. The government nevertheless concludes that the FDCA would preempt a pure design defect claim where, as here, the claim does not require the plaintiff to prove that the manufacturer knew or should have known of new and scientifically significant evidence that rendered the drug "misbranded" under federal law. [229](#)

A small point of agreement among the *Bartlett* parties, amici, and the Supreme Court is that the Court's latest ruling is to be narrowly drawn and construed, answering only the issue of whether a judgment based upon a design-defect claim against a generic manufacturer can stand. [230](#) The broader question of whether state tort liability should be employed as "a complementary form of drug regulation" [231](#) was saved for another day, and it appears that such a day will at least be scheduled for debate.

[\[*29\]](#) The stated purpose of the FDA's proposed rules is to "create parity" between brand name drug manufacturers and generic manufacturers, allowing generics to alter the drug label to include information (including warnings) specific to the generic product. [232](#) In so doing, the presumption is that generic manufacturers would avoid the pitfalls and protections of *Bartlett* and PLIVA, assuming responsibility for their label, and thus the liability as well. [233](#) Of course, the devil of the proposed change is in the details, and the FDA will also be cognizant of the costs and incentives involved with bringing generic products to market. [234](#) Moreover, if the FDA's goal is to "create parity," then it can be expected that interested parties will raise the issue of parity between FDA-approved drugs and medical devices, particularly since there are a

growing number of therapeutics where the distinction between drug and device is increasingly blurred. [235](#)

[\[*30\]](#)

IV. FDA Preemption and Medical Devices

A. Express Preemption: Riegel v. Medtronic, Inc.

As discussed earlier, the U.S. Supreme Court treats drugs and medical devices differently with respect to federal preemption of state product liability laws. [236](#) In the 2008 matter of Riegel v. Medtronic, Inc., [237](#) the Court found that the FDCA, including its Medical Device Amendments ("MDA"), [238](#) provides the exclusive enforcement mechanism to establish the safety of medical devices "approved" by the FDA. [239](#) Thus, the MDA arguably creates express [240](#) preemption for medical devices by statute, rebutting the usual presumption against federal preemption of state law for matters involving consumer health and safety:

(a) General Rule

Except as provided in subsection (b) of this section, no State of 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 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. [241](#) (Emphasis added.)

Some courts have interpreted the phrase "different from, or in addition to" only in reference to the duty of care, precluding the imposition of a higher state-law duty, but allowing state-law damages to be "tacked on"; [242](#) [\[*31\]](#) other courts have interpreted it to preclude either a higher duty of care or additional (state law) damages. [243](#)

While acknowledging the important rationale for vesting the FDA with exclusive authority over the approval process for drugs and medical devices, there remains, of course, the other side to the story. The FDA is equipped with a broad range of enforcement mechanisms for noncompliance

with the MDA. [244](#) Once again, however, none of these enforcement mechanisms include a private right of action that would enable an injured plaintiff to be compensated for her injury.

[245](#) The resultant shield not only denies reasonable redress to an injured plaintiff, but it also negates an important incentive for manufacturers to address the dangers posed by the use of their devices. It also provides a disincentive for becoming forthcoming and transparent about known or reasonably anticipated risks. [246](#)

In Riegel, the plaintiffs brought a damages action under New York law alleging that the catheter that ruptured in the lead plaintiff's coronary artery was inflated to a pressure that was higher than the Class III label indicated, which was approved by the FDA. [247](#) The plaintiffs' state-law

products liability action alleged that the catheter was defective. [248](#) The Supreme Court in Riegel denied the claim, finding that the MDA expressly preempted the plaintiffs' state law claim because it would impose a standard of care that is greater than the safety requirements required

by federal (FDA) regulations. [249](#) The defendant argued that under such circumstances, the legislature, in enacting the MDA, believed that it would [\[*32\]](#) be counter-productive to require manufacturers to be beholden to multiple different state-specific tort law regimes, some of which imposed a duty greater than the FDA. [250](#)

The Riegel Court thus concluded, specifically pursuant to the MDA, that a product, having been approved by the FDA, could not be held to a state law standard that was "different from, or in

addition to" the standard set forth under federal law. [251](#) In so holding, however, the Court

expressly reaffirmed its 1996 holding in *Medtronic, Inc. v. Lohr* [252](#) that § 510 K of the MDA (which states that medical devices can be "cleared" pursuant to a less onerous approval standard for devices substantially equivalent to a pre-existing device) does not preclude "traditional damages remedies for common law duties when those duties parallel federal

requirements." [253](#) The critical point is that the state law damages sought in Lohr (but not Riegel) were based upon a standard that was consistent with, and parallel to, the standards

required under federal law. [254](#)

While Riegel found, pursuant to the MDA, that liability under state law for the alleged product defect would be denied, the issue continues to linger. In particular, several subsequent federal courts have attempted to parse the scope of "implied" preemption in deciding whether all state law claims are preempted, or just those that are "different from, or in addition to" those available

under the federal law. [255](#) Riegel, which spoke to express preemption, arguably left open the possibility that a tort claim could be brought under principles of implied preemption as to a

state law that "parallels" federal law, which does not impose duties that are "different from, or in addition to" those available pursuant to federal law. [256](#) In Lohr, Justice Breyer emphasized this point in his concurrence, noting that he did [\[*33\]](#) not "find any indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field." [257](#) Latching onto this distinction, a number of cases have been brought in federal courts that interpreted Riegel, Lohr, and a third opinion, Buckman Co. v. Plaintiffs' Legal Committee, [258](#) regarding implied preemption. [259](#)

B. Implied Preemption: Buckman Co. v. Plaintiffs' Legal Committee

In many respects, the preemption issue continues to surface because the Riegel Court, while clearly articulating the principles of "express" preemption of medical devices pursuant to § 360(k) of the MDA, left open the scope (and thus limits) of the so-called "implied" preemption.

[260](#) The U.S. Supreme Court in Buckman Co. v. Plaintiffs' Legal Committee previously addressed this nuance in great detail, [261](#) but its interpretation has subsequently been disputed. [262](#)

In Buckman, the plaintiffs claimed that their injuries were a result of bone screws that had been used on their spines. [263](#) They brought a civil action in federal court against Buckman Co., a consulting company that assisted the manufacturer of the screws in "navigating the federal regulatory process for [those] devices." [264](#) The plaintiffs alleged that Buckman had made fraudulent representations to the FDA and that "but for" the false representations, they would not have been injured. [265](#) The District Court for the Eastern District of Pennsylvania dismissed the plaintiffs' so-called "fraud-on-the-FDA" claims on the ground that they were preempted by the MDA. [266](#) A divided panel of the Third Circuit Court of Appeals reversed, [\[*34\]](#) concluding that there was no preemption. [267](#) On appeal to the U.S. Supreme Court, the Buckman majority reversed the circuit panel, finding preemption on the basis that the claims under state law must "inevitably conflict" with the FDA's obligation to police this type of fraud.

[268](#) Furthermore, allowing this type of claim could impose a chilling effect on the pre-and post-marketing information provided to the FDA, resulting in the FDA being hampered in its efforts to evaluate applications for approval. [269](#) A concurring opinion emphasized the plaintiffs' inability to establish the "but for" causation that they alleged. [270](#)

Among the current controversy within the circuits is the reach of Buckman's implied preemption for claims of "fraud-on-the-FDA." Specifically, the Fifth, Seventh, and Ninth Circuits [271](#) have since ruled that Buckman only preempts specific fraud-on-the-FDA claims where such claims interfere with the exclusive authority of the FDA to enforce matters pursuant to the

FDCA. [272](#) Those that interpret Buckman to preempt all state court actions would preclude all traditional failure-to-warn and warranty claims when the alleged action violates a matter that

the FDCA regulates. [273](#) Those that interpret Buckman more narrowly find that so-called

"parallel" state claims are not preempted. [274](#) Parallel state claims are those that impose the same duties of care on the defendant - they merely add a state law damage action for failure to

comply with the federal duty. [275](#) For example, a federal court in the Eastern District of Louisiana found as follows:

[\[*35\]](#)

any claim based on the [federally regulated devices'] construction or composition, design, warnings, or express warranties would each specifically impose requirements different from or in addition to the FDA-approved requirements for the device. [276](#)

Such cases asserted state law tort theories such as failure-to-warn, manufacturing defects, breach of implied warranty, fraud, misrepresentation, etc. [277](#) To date, several cases have reached

the U.S. Court of Appeals and the legal conclusions are mixed. [278](#) In light of the deep split of opinion among the circuit courts, the issue is poised to precipitate a definitive review by the

U.S. Supreme Court. [279](#)

C. Analysis: Splitting the 5th, 6th, 7th, 8th, 9th, and 10th Circuits

One of the most recent cases to weigh in on the scope of implied preemption under Riegel, Lohr, and Buckman is a 2013 decision from the United States Court of Appeals for the Ninth Circuit in

Stengel v. Medtronic Inc. [280](#) In Stengel, the FDA had issued pre-marketing approval for implantable pain pumps and catheters that are used to deliver medication to a surgical site in the

vicinity of the spinal cord. [281](#) Richard Stengel was a patient who had a Medtronic pump

and catheter inserted, but soon thereafter lost strength and sensation in his legs. [282](#)

Although testing was done to determine the cause, Stengel's treating physician did not timely seek or detect the presence of a granuloma that was ultimately determined to have caused

Stengel's then-permanent paraplegia. [283](#) Meanwhile, the FDA, in [\[*36\]](#) conducting a routine audit, discovered numerous unreported adverse events concerning this pump and catheter - including granulomas - and issued a "Warning Letter" to Medtronic, thus requiring Medtronic

to distribute urgent warning letters to physicians who were using the products. [284](#) Medtronic was subsequently also forced to issue supplemental warnings before the FDA

eventually recalled the products. [285](#)

Stengel alleged that had his physician been timely notified by Medtronic of its post-marketing discovery of dangerous granulomas as required by the FDA, his physician would have tested for

granuloma and Stengel's permanent injury would have been avoided. [286](#) Medtronic countered that Stengel's lawsuit is exactly the type of state tort claim contemplated under Riegel's preemption doctrine: Arizona's damages provision would impose a legal standard that is "different from, or in addition to" the FDA's pre-marketing approval process of the pump and

catheter, the very criteria set forth in Riegel. [287](#)

The unanimous en banc court in Stengel [288](#) (overturning an earlier opinion of a 3-judge panel) examined Riegel and the MDA to conclude that "state requirements are preempted under the MDA only to the extent that they are "different from, or in addition to" the requirements

imposed by federal law." [289](#) Thus, the court interpreted these cases to allow "parallel" state

damage claims that that are neither different from nor in addition to those of the FDCA. [290](#)

The court relied substantially upon the Supreme Court's decision in *Medtronic, Inc. v. Lohr*,

[291](#) which found that § 360(k) of the MDA does not preclude "traditional" common law tort

remedies to the extent that they are not inconsistent with federal requirements. [292](#) The Stengel court found that there was enough ambiguity in the *Lohr*, *Buckman*, and *Riegel* precedent to avoid concluding that Congress and the FDA intended to "deprive the States of any

role in protecting consumers from the dangers inherent in many medical devices." [293](#)

[\[*37\]](#) Latching on to this distinction between express and implied preemption, the en banc Ninth Circuit allowed the plaintiff to bring his state-law "failure to warn" claims for injuries

resulting from an FDA-approved medical device. [294](#) The court specifically limited its reach to circumstances where state law does not impose safety requirements that are "different

from, or in addition to" those required by the FDA. [295](#) In so concluding, the Stengel court commented:

Given the ambiguities in the statute and the scope of the preclusion that would occur otherwise ... we cannot accept Medtronic's argument that ... Congress clearly signaled its intent to deprive the States of any role in protecting consumers from the dangers inherent in many medical

devices. [296](#)

On this preemption issue, Stengel stands substantially in unison with the MDA cases in the Fifth and Seventh circuits, which decided that parallel state-law claims are not preempted. [297](#) In

Hughes v. Boston Scientific Corp., [298](#) for example, the Fifth Circuit Court of Appeals concluded that Boston Scientific's alleged negligent failure to report "serious injuries" and "malfunctions" of the device as required by the FDA (and deemed negligent under Mississippi

state tort law) would not be preempted. [299](#) The Fifth Circuit held similarly in Bass v.

Stryker, [300](#) stating that negligence claims premised upon failure-to-warn claims would be

preempted, but not those based upon negligence in manufacturing. [301](#) Similarly, in Bausch

v. Stryker Corp., [302](#) the Seventh Circuit Court of Appeals decided that the alleged defective manufacture of a device in violation of the MDA's manufacturing regulations would

not be preempted. [303](#)

[\[*38\]](#) The Tenth Circuit Court of Appeals in Howard v. Zimmer, Inc. [304](#) reached a

similar conclusion despite a circuitous procedural route. [305](#) Howard's initial appeal occurred in the Sixth Circuit through multidistrict litigation, but eventually landed in the Tenth

Circuit, which certified the preemption question to the Oklahoma Supreme Court. [306](#)

Howard involved a knee replacement (implant) that supposedly failed, and required removal due

to the implant's inability to bond with the plaintiff's bone. [307](#) The purported cause of the failure was an oily residue left on the device, which was in violation of the manufacturing

standards required by the FDA. [308](#) The plaintiff alleged that the violation of the

manufacturing standard constituted negligence per se. [309](#) Although the defendant urged that negligence per se cannot be predicated upon violation of a regulation (instead of a statute),

the Oklahoma Supreme Court disagreed. [310](#) It established that (1) Oklahoma law does permit a private party (plaintiff) to assert a parallel claim for negligence per se, and (2) negligence per se can be based upon violation of a regulation when the enforcement of the

regulation falls within the function of a governmental entity. [311](#)

In contrast to Stengel, Hughes, Bausch, and Howard, appellate courts in the Sixth and Eighth circuits issued opinions that were somewhat at odds with the narrow interpretation of their sister

circuits. [312](#) In *Garcia v. Wyeth-Ayerst Labs*, [313](#) the Sixth Circuit Court of Appeals determined that Buckman prohibits reliance on findings of the state court to establish that a defendant manufacturer misrepresented or withheld important safety data [\[*39\]](#) from the FDA.

[314](#) Though not entirely on point, the Eighth Circuit Court of Appeals in *In re Medtronic,*

Inc., Sprint Fidelis Leads Products Liability Litigation [315](#) characterized the claims under state law, which stated that the FDA was not provided with adequate information, and were

"simply an attempt by private parties to enforce the MDA." [316](#)

Since early 2013, a number of lower courts, [317](#) several in the Ninth circuit, [318](#) and

the Oklahoma Supreme Court [319](#) have followed the Stengel precedent. [320](#) For example, the federal district court for the central district of California followed Stengel in the

matter of *Simmons v. Boston Scientific Corp. et al.* [321](#) In *Simmons*, a defibrillator

allegedly malfunctioned, causing injury to the plaintiff. [322](#) The defendants, of course,

argued that the plaintiff's claim was preempted under Riegel and the MDA. [323](#) In an effort to overcome Riegel preemption, the plaintiff alleged that the defendants also violated parallel

state law duties, including failure-to-warn, pursuant to the recent Stengel precedent. [324](#)

The district court recognized that in the absence of Stengel, Riegel preemption likely would have prevailed since the defendant argued it would be required to "give warnings to patients or

physicians different from or broader than those required by FDA regulations." [325](#)

Although the *Simmons* court recognized that the plaintiff's claims might now prevail under

Stengel, the plaintiffs ultimately failed anyway on procedural grounds. [326](#)

[\[*40\]](#) The split among the circuits concerning the scope of MDA preemption focuses squarely on the issue of whether both implied preemption under the rationale set forth in *Buckman*, ("this sort of litigation would exert an extraneous pull on the scheme established by Congress and is

therefore pre-empted" [327](#)) and express preemption under Riegel (the FDA "may ... approve devices that present great risks if they nonetheless offer great benefits in light of the

available alternatives" [328](#)) leaves room for the "parallel" cause of action identified in

Stengel, Hughes, and Bausch. [329](#)

Riley v. Cordis Corp., [330](#) a federal district court opinion from the district of Minnesota, provides a thoughtful interpretation of Buckman, Lohr, and Riegel, concluding that there is only

a "narrow gap" of medical device cases that would survive MDA preemption. [331](#) Specifically, the court determined that "the plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360(k)(a)), but the plaintiff must not be suing because the conduct violates the FDCA (since such a claim would be impliedly preempted

under Buckman)." [332](#) So, for example, parallel state law claims that allege misrepresentation or nondisclosure (whether fraudulent or negligent) might fit through the Riley "narrow gap" since "the state-law claim is in substance ... a claim for violating the FDCA - that

is, when the state claim would not exist if the FDCA did not exist." [333](#) Furthermore, Riley decided that state law claims "premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA" may survive

preemption under Buckman. [334](#) The courts in the Hughes, Bausch, and Stengel cases may have gone further, finding that so-called parallel state-law damage claims are not preempted,

except to the extent that they clearly assert "fraud on the FDA." [335](#)

[\[*41\]](#)

V. MDA, Preemption, and Off-Label Use of Medical Devices

A related issue that is yet unresolved is whether off-label uses of medical devices would survive

MDA preemption. [336](#) On the one hand, Buckman contemplated the burden that manufacturers face in seeking marketing approval each time a "reasonable" off-label use is

contemplated; [337](#) on the other hand, medical devices that are granted through pre-marketing approval (even on the basis of false, misleading, or incomplete information) for one

use can do significant damage in the medical setting if used differently. [338](#) With broad implied preemption, device manufacturers might be faced with an incentive to seek FDA approval for the most minimal contemplated use - and thereafter market the product for

additional, perhaps largely untested, uses - with impunity. [339](#)

A recent example of an alleged off-label use of a medical device that a state court determined might fit through the MDA "implied preemption" window concerned use of products that included INFUSE - a genetically engineered protein that has been widely used in spinal surgeries

- and is currently the subject of a congressional investigation. [340](#) In Cabana v. Stryker

Biotech, LLC and Medtronic, Inc., [341](#) a state court action in California, the plaintiff, April

Cabana, claimed that she initially suffered permanent, debilitating injuries in her spinal column as a result of two products (Calstrux and OP-1) manufactured by Stryker that were mixed

together in a manner not approved by the FDA. [342](#) Cabana alleged that Stryker promoted

use of the products off-label, knowing that doing so could result in harm. [343](#) Stryker was subsequently indicted in federal court for illegal marketing of the products, and two of its sales

managers pled guilty [\[*42\]](#) to off-label promotion. [344](#) In a subsequent surgery to address her poor result, Cabana alleged that the surgeon used a Medtronic INFUSE bone graft, also off-

label, which failed to correct her condition. [345](#) It was later reported in The Spine Journal that Medtronic failed to accurately report the side effects from the clinical trials, and that many of the investigators who worked on the studies had significant financial ties to Medtronic.

[346](#)

Medtronic defended its action on the basis that Cabana's claim should be expressly preempted by

the MDA since the devices received pre-marketing approval by the FDA. [347](#) In refusing to dismiss the matter, the California trial court concluded that because it is alleged that defendants "promoted the use of its devices in violation of federal requirements... . Riegel is not authority

that plaintiff's claims ... are preempted here." [348](#) In support of Cabana's claim that the INFUSE device was used off-label and therefore in violation of its FDA approval, Cabana offered evidence that Medtronic used a paid consultant to train her own physician in use of the

bone graft for this off-label application. [349](#) In 2012, Medtronic settled for \$ 85 million in a shareholder lawsuit, which alleged that Medtronic had failed to divulge that more than 85% of

INFUSE sales were based upon off-label uses. [350](#)

VI. Conclusion: "Parallel" Claims as an Interim Measure Toward Parity for Drugs and Devices

In the context of medical devices, three U.S. Supreme Court cases [351](#) create the foundation for federal preemption under the FDCA, and specifically, the possibility of parallel state claims. These cases, because they are governed by the MDA, follow a different path from the Supreme

Court cases that guide federal preemption in the context of FDA-approved drugs. [352](#) To summarize the issue as to medical devices, Lohr determined that the FDCA does not preempt "a traditional damages remedy for [\[*43\]](#) violations of common-law duties when those duties

parallel federal requirements." [353](#) Buckman supports the bringing of state law tort claims to the extent that a plaintiff "relies on traditional state tort law[,]" but rejects such claims if the

FDCA provides "a critical element in [the] case." [354](#) In order to determine whether a state-

law claim could prevail, Riegel provides the guidance, albeit in the context of drugs. There, the Court established a test for determining whether a state-law tort claim could proceed: it would ask whether state law imposes a safety requirement that is "different from, or in addition to" the

federal requirement. [355](#) This concept of a "parallel" [356](#) claim now awaits more precise definition by the U.S. Supreme Court.

Until that time, the circuit courts in *Bausch*, [357](#) *Hughes*, [358](#) and, most recently,

Stengel, [359](#) can stand for the principle that it is yet unclear whether the FDCA actually intended to impose different tort rules for drugs and devices, particularly where state and federal law duties are parallel to one another. *Stengel*, in particular, refused to reach what would otherwise be the inevitable conclusion that Congress intended to "deprive the States of any role

in protecting consumers from the dangers inherent in many medical devices." [360](#) The government argued as much in its amicus curiae brief in *Stengel*, wherein it explicitly challenged

the Ninth Circuit Court of Appeals' interpretation of parallel claims. [361](#) Curiously, however, at the same time, it also successfully took a position against certiorari in the U.S. Supreme Court where the issues might have been vetted and resolved. So while the MDA in recent years has largely shielded medical device manufacturers from liability pursuant to state tort law, it now appears that the climate is shifting, and it is only a matter of time before there is more activity in the circuit courts that lead to another case making its way to the U.S. Supreme Court. Until that time, *Stengel* provides compelling arguments, including the voice of the government, in favor of allowing state-law tort claims against manufacturers of medical devices.

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Footnotes

- [1](#)

[133 S. Ct. 2466 \(2013\)](#).

- [2](#)

See [id. at 2470](#) (holding that federal law preempts state design regarding generic drug adequacy of a warning in design-defect liability).

- [3](#)

See [Wyeth v. Levine, 555 U.S. 555, 581 \(2009\)](#) (concluding that the plaintiff's state law failure-to-warn claim was not preempted by defendant's federal-law obligations and that Congress' purpose was not obstructed).

- [4](#)

See [PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2572 \(2011\)](#) (holding that the federal drug regulations for generic drug manufacturers preempt the state-law claims that conflict with those regulations).

- [5](#)

See *id.* (holding that where federal drug regulations directly conflict with a duty to warn imposed by state law, the state law will be preempted).

- [6](#)

See *id.* at 2574-75 (stating that the FDA regulates warning labels).

- [7](#)

See [Bartlett, 133 S. Ct. at 2470](#) (explaining the design-defect cause of action against the generic manufacturer, and the inherent problems with such a cause of action).

- [8](#)

See Facts About Generic Drugs, U.S. Food & Drug Admin., <http://www.fda.gov.ezproxy.library.tufts.edu/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> (last updated Sept. 19, 2012) (noting the differences between generic and brand name drugs, which include variations in inactive chemical ingredients and rate of absorption).

- [9](#)

See [Bartlett, 133 S. Ct. at 2471-72](#) (referencing the plaintiff's design-defect claim); see also [PLIVA, 131 S. Ct. at 2572](#) (framing the question as whether or not the federal drug regulations preempt state law claims).

- [10](#)

See [Wyeth v. Levine, 555 U.S. 555, 581 \(2009\)](#) (allowing the state failure-to-warn claim as supported by the history of co-existence between state and federal law and the FDA's recognition of state law remedies).

- [11](#)

See [PLIVA, 131 S. Ct. at 2571](#) (holding that the federal regulations applicable to generic drug manufacturers preempt state law claims).

- [12](#)

See [Riegel v. Medtronic, Inc., 552 U.S. 312, 330 \(2008\)](#) (finding that manufacturer liability for state product liability claims are preempted to the extent that the state law requirements are different from, or in addition to the federal requirements).

- [13](#)

See [21 U.S.C. § 360\(k\)\(a\)\(1\)](#) (2012) (prohibiting the imposition of state law requirements different from, or in addition to federal law requirements); see also [Riegel, 552 U.S. at 330](#) (noting that state law requirements are preempted to the extent that they are different from, or in addition to federal requirements).

- [14](#)

See [Bartlett, 133 S. Ct. at 2469, 2470](#) (holding that state law design-defect claims based on the adequacy of the warning label are preempted).

- [15](#)

See Alexander Gaffney, FDA Proposes Groundbreaking Overhaul of Generic Drug Labeling Regulation, Reg. Aff. Prof. Soc'y (Nov. 11, 2013), <http://www.raps.org/regulatoryDetail.aspx?id=9625#> (describing the agenda following the Bartlett decision as including a proposed rule for generic manufacturers to apply for a labeling change).

- [16](#)

See Justin Hakes, U.S. Chamber Decries FDA's Proposed Rule on Generic Prescription Drug Labeling, Bus. Wire (Nov. 8, 2013), <http://www.businesswire.com/news/home/20131108005889/en/U.S.-Chamber-Decries-FDA%E2%80%99s-Proposed-Rule-> Generic#.VBD18PldWWY (citing concerns that the proposed rule would allow a flood of litigation against generic drug manufacturers).

- [17](#)

Cf. [Messner v. Medtronic, Inc., 975 N.Y.S.2d 367 \(N.Y. Sup. Ct. 2013\)](#) (unpublished opinion) (explaining that the Supreme Court did not delineate what state parallel claims would survive preemption, and that the Fifth, Seventh, Ninth, and possibly Eighth Circuits, have allowed parallel state law causes of action for certain violations).

- [18](#)

See [Alton v. Medtronic, Inc., 970 F. Supp. 2d 1069, 1084 \(D. Or. 2013\)](#) (discussing the issue of whether or not all parallel state law claims are preempted by FDA approval of medical devices).

- [19](#)

See *infra* Parts IV, V.

- [20](#)

See [21 U.S.C. § 301](#) (2012).

- [21](#)

See generally [21 U.S.C. § 393\(a\)-\(b\)](#) (2012) (establishing the FDA's mission as including the oversight of regulated products, including drugs and devices); see, e.g., *id.* § 355(b)(1)(B)-(F) (outlining the FDA's oversight of new drug production, sales, and marketing); see also, e.g., *id.* § 360e(c)(1) (outlining the FDA's oversight of new devices, including production, sales, and marketing).

- [22](#)

See [21 U.S.C. § 355](#) (detailing the application process for new drugs); see also [Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294, 1296 \(11th Cir. 2003\)](#) (citing the inclusion of efficacy studies in new drug applications).

- [23](#)
[21 U.S.C. § 355\(b\)\(1\)\(A\)](#).

- [24](#)
[21 C.F.R. § 314.50\(d\)\(5\)\(iv\) \(2013\)](#).

- [25](#)
See [Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 140 \(2000\)](#) (describing the FDA's cost benefit analysis involved in approving new drugs).

- [26](#)
See [Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2471 \(2013\)](#) (describing the approval process for generic drugs, generally).

- [27](#)
See *id.* (recounting the adoption of the Hatch-Waxman Act).

- [28](#)
See Joel Graham, Note, The Legality of Hatch-Waxman Pharmaceutical Settlements: Is the Terazosin Test the Proper Prescription? [84 Wash. U. L. Rev. 429, 434 \(2006\)](#) (describing how Hatch-Waxman encourages "piggybacking").

- [29](#)
See [Bartlett, 133 S. Ct. at 2471](#) (describing the aspects of chemical equivalency mandated by Hatch-Waxman).

- [30](#)
See [21 C.F.R § 314.50 \(2013\)](#) (describing the approval of a new drug based on the FDA's safety determination, which also allows the manufacturer to finalize the proposed label).

- [31](#)

See [21 U.S.C. § 352](#)(a), (e), (n) (2012) (prescribing the factors that the drug label must meet in order to avoid being deemed misbranded).

- [32](#)

See *id.* § 355(d) (outlining the classification of misbranding by the FDA).

- [33](#)

See [Bartlett, 133 S. Ct. at 2471](#) (noting that generic manufacturers are barred from changing the drug label).

- [34](#)

See [21 C.F.R. § 314.150\(b\)\(10\) \(2014\)](#) (explaining that approval can be withdrawn if the labeling for the drug product is "no longer consistent" with the listed drug that the abbreviated NDA refers to).

- [35](#)

See *infra* note 37 and accompanying text. Thus, while the FDA prohibits a manufacturer from promoting a drug for an unapproved indication, once a drug is FDA-approved for at least one indication and is placed into interstate commerce, medical providers are free to prescribe it for any purpose, regardless of its labeling, subject only to professional standards. See [United States v. Caronia, 703 F.3d 149, 152-53](#), (2nd Cir. 2012). When a drug is used for a condition or in a manner that deviates from that described in the FDA-approved drug label, the use is considered "off-label." This includes use of the drug to treat a different medical condition or disease, as well as use in a dosage or route that deviates from that described in the approved label. See *infra* note 37 and accompanying text.

- [36](#)

See Michael D. Green & William B. Schultz, Tort Law Deference to FDA Regulation of Medical Devices, [88 Geo. L.J. 2119, 2133 \(2000\)](#) (noting that physicians are permitted to prescribe drugs for off-label uses); see also Christopher M. Wittich et al., Ten Common Questions (and Their Answers) About Off-label Drug Use, 87 *Mayo Clinic Proc.* 982, 983 (2006) (explaining that physicians frequently prescribe off-label drugs).

- [37](#)

See Wittich et al., supra note 36 (explaining that physicians frequently prescribe off-label drugs).

- [38](#)

Statement, Am. Soc'y of Hosp. Pharm., ASHP Statement on the Use of Medications for Unlabeled Uses (1992) (on file with author), available at <http://www.ashp.org/DocLibrary/BestPractices/FormStUnlabeled.aspx>.

- [39](#)

See [21 C.F.R. § 860.3\(c\)\(1\)-\(2\)](#) (2014) (defining what makes devices Class I, II, or III, differentiated by level of risk).

- [40](#)

See § 860.3(c)(3) (defining Class III devices as those where the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential reasonable risk of illness or injury).

- [41](#)

See [Riegel v. Medtronic, Inc., 552 U.S. 312, 316-17 \(2008\)](#) (explaining the different classes of devices); see also [21 U.S.C. § 860\(a\)\(1\)\(A\)](#) (2012).

- [42](#)

See Daniel Kazhdan, Other Developments in Intellectual Property: Wyeth and PLIVA: The Law of Inadequate Drug Labeling, [27 Berkeley Tech. L.J. 893, 904 \(2012\)](#) (citing a 2002 study published in the Journal of the American Medical Association describing the statistics of serious warnings and market removals).

- [43](#)

See, e.g., [Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 343 \(2001\)](#) (explaining that the plaintiffs contend that the petitioner made fraudulent representations to the FDA in order to obtain approval).

- [44](#)

See, e.g., [Feldman v. Lederle Lab., 592 A.2d 1176, 1179 \(N.J.1991\)](#) (stating that the package contained no warning of the potential side effects of tooth discoloration).

- [45](#)

See [Cooper Labs., Inc. v. Comm'r, Fed. Food & Drug Admin., 501 F.2d 772, 786 \(D.C. Cir. 1974\)](#) (holding that the FDA's rejection of a new drug was proper because evidence supporting the drug's efficacy did not meet statutory standards).

- [46](#)

See Jason Lazarou et al., Incidence of Adverse Drug Reactions in Hospitalized Patients, 279 JAMA 1200, 1202 (1998), available at <http://jama.jamanetwork.com.ezproxy.library.tufts.edu/article.aspx?articleid=187436> (estimating that in 1994, approximately 106,000 deaths in the United States were due to an adverse drug reaction).

- [47](#)

See Bryan G. Scott & Elizabeth K. Strickland, Recent Developments in Federal Preemption of Pharmaceutical Drug and Medical Device Product Liability Claims, The Defender, Fall 2009, at 22, available at <http://www.spilmanlaw.com/media%20content/media-content/documents/preemption-developments.pdf> (noting the debate over the past few years over the interplay between state tort laws, and federal regulation of pharmaceutical drugs and medical devices).

- [48](#)

See [Bailey v. Johnson, 48 F.3d 965, 968 \(6th Cir. 1995\)](#) (noting that Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA).

- [49](#)

[Wyeth v. Levine, 555 U.S. 555, 612 \(2009\)](#) (Alito, J., dissenting) ("Drug labeling by jury verdict undermines both our broader preemption jurisprudence and the broader workability of the federal drug-labeling regime.").

- [50](#)

[Id. at 626](#) (explaining that without the FDA, consumers could suffer since juries in all 50 states would be free to contradict the FDA, and that the benefit of the FDA is the conveyance of warnings in one voice, rather than in 50 potentially conflicting ones).

- [51](#)

See Jason C. Miller, Note, When and How to Defer to the FDA: Learning from Michigan's Regulatory Compliance Defense, [15 Mich. Telecomm. & Tech. L. Rev. 565, 566 \(2009\)](#) (explaining that federal regulations preempting state tort laws avoid the asymmetry in the state tort systems).

- [52](#)

[Id. at 574](#) (explaining that giving FDA exclusive authority creates accountability not afforded to juries).

- [53](#)

[Id. at 579-80](#) (explaining that Michigan has excluded the evolving list of drugs as a basis for a liability action).

- [54](#)

See [PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 924 \(9th Cir. 2010\)](#) (explaining that the Supreme Court has interpreted § 337(a) of the FDCA to mean that the federal government, and not private litigants, are authorized to file suit for noncompliance with medical provisions).

- [55](#)

See Miller, *supra* note 51, at 569 (explaining that only private tort litigation can offer a remedy in the event that the FDA approves defective drugs).

- [56](#)

[Wyeth v. Levine, 555 U.S. 555, 581 \(2009\)](#) (concluding that Congress has repeatedly declined to preempt state law, and that the FDA's recent position that state tort suits interfere with the statutory mandate is entitled to no weight).

- [57](#)

Id.

- [58](#)

[Id. at 559.](#)

- [59](#)

Id. (noting that Phenergan is Wyeth's brand name for promethazine hydrochloride, an antihistamine used to treat nausea).

- [60](#)

Id. (explaining that the plaintiff, Levine, developed gangrene, and doctors amputated her right hand, and eventually her entire arm).

- [61](#)

See [id. at 559-60](#) (arguing that although a gangrene warning was included on Phenergan's label, the label should have included a warning against administering the drug via the higher-risk intravenous IV-push method, instead advising clinicians to use the safer IV-drip method of injection).

- [62](#)

[Id. at 560](#) (explaining that Wyeth argued that Levine's failure-to-warn claims were preempted by federal law).

- [63](#)

[Id. at 562.](#)

- [64](#)

[Id. at 563.](#)

- [65](#)

Id. (concluding that as long as federal law and state law are not in conflict, then state law judgment is not preempted).

- [66](#)

[Id. at 581](#) (finding that state failure-to-warn cases do not obstruct federal regulation).

- [67](#)

Compare [PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2577-78 \(2011\)](#) (noting that it was impossible for manufacturers to comply with both federal and state law, requiring state law to be preempted), with [Mensing v. Wyeth, 588 F.3d 603, 614 \(8th Cir. 2009\)](#) (finding Mensing's claim can proceed and federal law requires such cases proceed), and [Demahy v. Actavis, 593 F.3d 428, 449 \(5th Cir. 2010\)](#) (noting that if Congress had intended to prevent state tort law cases, Congress would have clearly expressed that intent).

- [68](#)

[PLIVA, 131 S. Ct. at 2572.](#)

- [69](#)

Id.

- [70](#)

[Id. at 2572-73.](#)

- [71](#)

[Id. at 2570](#) (noting that the Plaintiffs argued that the manufacturers inadequately labeled the metoclopramide by failing to warn of the risks of long term use).

- [72](#)

[Id. at 2571, 2582.](#)

- [73](#)

See [id. at 2580-81](#) (noting that any change to the drug would require the manufacturer to seek FDA approval).

- [74](#)

See [id. at 2581](#) (noting that because the pharmacist filled the prescription with the generic medication and not the brand-name, the state-tort claim was preempted).

- [75](#)

See [Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 37 \(1st Cir. 2012\)](#), cert. granted, [133 S. Ct. 694 \(2012\)](#), and rev'd, [133 S. Ct. 2466 \(2013\)](#) (citing [PLIVA, 131 S. Ct. at 2578 \(2011\)](#) ("Generic drug manufacturers, unlike brand-name manufacturers, cannot unilaterally change their labels").

- [76](#)

See [552 U.S. 312, 322 \(2008\)](#) (noting that the Court has consistently held that FDA approval does not preempt state tort suits).

- [77](#)

Compare [Riegel, 552 U.S. at 345](#) (holding that [21 U.S.C. § 360\(k\)\(a\)](#) does not preempt Riegel's suit), with [Wyeth v. Levine, 555 U.S. 555, 628](#) (holding that state law is preempted).

- [78](#)

See [Riegel, 552 U.S. at 320](#) (noting that Riegel alleged that the catheter's design, label, and manufacturing violated New York common law).

- [79](#)

Id. (noting the Evergreen Balloon Catheter had received pre-marketing approval from the FDA).

- [80](#)

See *id.* at 316-17 (noting that there are three classes, with Class III receiving the highest level of scrutiny).

- [81](#)

See *id.* at 317-20 (noting that the catheter is a Class III device, which is the highest level of classification).

- [82](#)

See *id.* at 320 (noting that the Evergreen Balloon Catheter received pre-marketing approval by the FDA).

- [83](#)

Id. at 321 n.2 (noting that the Second Circuit Court affirmed the district court's decision granting summary judgment).

- [84](#)

Medical Device Amendments of 1976, [21 U.S.C. § 360](#) (2012).

- [85](#)

See [Riegel, 552 U.S. at 316](#) (stating that Congress passed the MDA, and included an express preemption provision).

- [86](#)

See [id. at 322-23](#) (noting that unlike general labeling duties, pre-marketing approval is specific to individual devices and is not an exemption from federal safety review); see [id. at 324-25](#) (stating that the Court has consistently found federal statutes to preempt state tort claims).

- [87](#)

[133 S. Ct. 2466 \(2013\)](#).

- [88](#)

See [id. at 2478](#) (observing that the plaintiff advanced the stop-selling rationale).

- [89](#)

See *id.* (noting that Bartlett argued the stop-selling rationale).

- [90](#)

See [id. at 2488](#) (observing that the design-defect claim is for an "unreasonably dangerous" product).

- [91](#)

See [id. at 2472, 2480](#) (noting that neither Mensing nor Levine had addressed this issue).

- [92](#)

See Catherine M. Sharkey, What Riegel Portends for FDA Preemption of a State Law Products Liability Claim, [103 Nw. U. L. Rev. 437, 440 \(2009\)](#) (defining express preemption as a statutory text that prohibits state-tort law claims).

- [93](#)

See *id.* (noting that the intent of the MDA was to preempt state tort cases that prevent production of devices that could help those in need).

- [94](#)

See Richard A. Epstein, The Case for Field Preemption of State Laws in Drug Cases, [103 Nw. U. L. Rev. 463, 464 \(2009\)](#) (defining implied preemption as a conflict between federal and state statutes, where the intended effect of the federal statute cannot be carried out).

- [95](#)

See [id. at 470](#) (noting that the process of FDA approval still requires costly input for litigation).

- [96](#)

See [Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 348 \(2001\)](#); see, e.g., Michael P. Moreland, Tort Reform by Regulation: FDA Prescription Drug Labeling Rules and Preemption of State Tort Claims, 1 J. Health & Life Sci. L. 39, 57 (2007) (noting that the suit claimed that the manufacturer lied to the FDA, and therefore was improperly given market clearance).

- [97](#)

See [Buckman, 531 U.S. at 352](#) (noting that there is clear evidence that Congress meant that the Medical Device Amendments of 1976 be enforced exclusively by the Federal Government).

- [98](#)

[Id. at 347.](#)

- [99](#)

[Id. at 351](#) (holding that disclosures to the FDA may be deemed appropriate by the administration, but may be judged insufficient in a state court).

- [100](#)

[Id. at 350](#) (explaining that it will be impractical for manufacturers, and will increase the burden of manufacturers to comply with FDA's detailed regulatory regime and the 50 state tort regimes).

- [101](#)

See *id.* (noting that manufacturers might be exposed to unpredictable civil liability, and may be discouraged from seeking FDA approval for their devices).

- [102](#)

Compare [Wyeth v. Levine, 555 U.S. 555, 574](#) (explaining that for drug products, Congress intended state rights of action to provide appropriate relief for injured consumers), with [PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2580, 2581 \(2011\)](#) (holding that a manufacturer cannot independently satisfy state duties for preemption purposes without the FDA's permission), and [Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 584 \(2013\)](#) (concluding that compliance with federal and state duties was not possible, and impossibility preemption is inappropriate).

- [103](#)

[133 S. Ct. 2466 \(2013\)](#).

- [104](#)

[Id. at 2471](#). The FDA approved generic "sulindac" in 1978 under the brand name Clinoril, followed by several generic versions after patent expiration, including one that Mutual Pharmaceutical Co. would manufacture. [Id. at 2471](#).

- [105](#)

Toxic epidermal necrolysis is a rare but severe condition where the epidermis (upper layer of the skin) can separate from the skin. Thomas Harr & Lars E. French, Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome, Orphanet J. Rare Diseases (Dec. 16, 2010), available at <http://www.ojrd.com.ezproxy.library.tufts.edu/content/5/1/39>.

- [106](#)

[Id. at 2471-72](#).

- [107](#)

[Bartlett v. Mut. Pharm. Co., 731 F. Supp. 2d 135, 142 \(D.N.H. 2010\)](#) (explaining that Sulindac's label listed "severe skin reactions" under its "Warnings" section, and Stevens-Johnson Syndrome and toxic epidermal necrolysis under its "Adverse Reactions" section), *aff'd*, [678 F.3d 30, 37 \(1st Cir. 2012\)](#), *cert. granted*, [133 S. Ct. 694 \(2012\)](#), and *rev'd*, [133 S. Ct. 2466 \(2013\)](#).

- [108](#)

Id. (noting that the label listed Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis as potential adverse reactions in its "Adverse Reactions" section). Subsequent to the plaintiff's injury in 2005, the FDA completed a comprehensive review of NSAIDs and recommended that the label of all brand and generic forms be amended to specifically warn of toxic epidermal necrolysis. [Bartlett, 133 S. Ct. at 2472](#).

- [109](#)

See [Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 34 \(1st Cir. 2012\)](#) (describing that Bartlett's skin lesions involved 60-65% of her body), cert. granted, [133 S. Ct. 694 \(2012\)](#), and rev'd, [133 S. Ct. 2466 \(2013\)](#); see also [Bartlett, 731 F. Supp. 2d at 142](#) (noting that Bartlett was in the hospital for three months, spending two months in a medically induced coma, and suffered permanent injuries, including blindness).

- [110](#)

See [Bartlett, 678 F.3d at 34](#) (stating that Bartlett brought claims for breach of warranty, fraud, negligence, design-defect, failure-to-warn, and manufacturing defect); see also [Bartlett, 133 S. Ct. at 2471-72](#) (stating that NSAIDs, including Sulindac, were known in 2004 to potentially cause toxic epidermal necrolysis).

- [111](#)

[Bartlett, 678 F.3d at 37](#). Bartlett stands in contrast to prior lower court opinions that uniformly rejected the concept that the generic drug should not have been marketed at all. See, e.g., [Moore v. Mylan, Inc. 840 F. Supp. 2d 1337, 1352 n. 14 \(N.D. Ga. 2012\)](#) (noting that any negligence claim is preempted because the plaintiff has not shown that there is a state law that asks the manufacturer to stop producing the drug when the FDA has granted authority to do so); *Coney v. Mylan Pharms., Inc.*, No. 6:11-cv-35, [2012 WL 170143, at 5](#) (S.D. Ga. Jan. 19, 2012) (explaining that if a state law prohibits a manufacturer from doing what federal law explicitly requires the manufacturer to do, it confers supremacy upon the state law); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.* (No. 11), No. 08-008 (GEB-LHG), 2011 WL 5903623, at 6 (D.N.J. Nov. 21, 2011) (holding that FDA statutory requirements preempts any conflicting tort duty arising under state law); [Lance v. Wyeth, 4 A.3d 160 \(Pa. Super. Ct. 2010\)](#) (declining to impose on manufacturers a common law duty to recall a drug in the absence of a state statute or administrative mandate to recall a drug).

- [112](#)

[Bartlett, 678 F.3d at 43](#).

- [113](#)

[Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466 \(2013\)](#).

- [114](#)

[Bartlett, 678 F.3d at 34-35](#) (citations omitted).

- [115](#)

[Id. at 41.](#)

- [116](#)

[Id. at 34-36](#) (noting that by trial date, Bartlett's remaining theory of design-defect was that Sulindac's risks outweighed its benefits).

- [117](#)

[Id. at 41](#) (stating that under the current law, the original manufacturer and not the generic manufacturer can alter the label); see also [Bartlett, 133 S. Ct. at 2472](#) (explaining that in 2005, after Ms. Bartlett's injury, the FDA recommended changes to the warnings of all NSAIDs, including Sulindac, to specifically identify toxic epidermal necrolysis as an adverse side effect).

- [118](#)

Compare [Bartlett, 678 F.3d at 37](#) (explaining that the statute contains no general preemption provision, and that state law serves as a "complementary form of drug regulation"), with [Moore v. Mylan, Inc., 840 F. Supp. 2d 1337 \(N.D. Ga. 2012\)](#) (concluding that because the manufacturer was prevented by federal law from changing labels to conform with a state law, the failure-to-warn claim is preempted), and *Coney v. Mylan Pharms., Inc.*, No. 6:11-cv-35, [2012 WL 170143](#) (S.D. Ga. Jan. 19, 2012) (holding that it would confer supremacy to state law if the manufacturer is prohibited by state law from doing what federal law requires it to do), and *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. 11), No. 08-008 (GEB-LHG)*, [2011 WL 5903623](#) (D.N.J. Nov. 21, 2011) (stating that federal duty preempts plaintiff's claims), and [Lance v. Wyeth, 4 A.3d 160 \(Pa. Super. Ct. 2010\)](#) (declining to impose upon a drug manufacturer a common law duty to recall a drug, and stating that the FDA has the power to withdraw approval of prescription drugs).

- [119](#)

[Brief for Petitioner at 24, Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466 \(2013\)](#) (No. 12-142) (stating that Congress has vested the FDA with the responsibility to determine if a product is safe and effective prior to entering the interstate market).

- [120](#)

Id. at 28 (arguing that it would be inconsistent with the FDCA to require a manufacturer to recall a product approved by the FDA if a jury under state tort law finds the product unsafe).

- [121](#)

Id. (describing that such state-by-state considerations would undermine the FDA's drug-safety determinations).

- [122](#)

[555 U.S. 555 \(2009\)](#).

- [123](#)

[Id. at 581](#) (holding that the FDA's position that state tort suits interfere with its statutory mandate has no weight).

- [124](#)

[Id. at 558](#) (stating that the question was whether FDA approval provides a manufacturer with a complete defense to a state tort action); see also [PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2573 \(2011\)](#) (explaining that the issue was whether the consumers' claims for failure to provide adequate labels are preempted by federal law).

- [125](#)

[PLIVA, 131 S. Ct. at 2574](#) (stating that a brand-name manufacturer is responsible for accuracy and adequacy of labels, while a generic manufacturer is responsible for ensuring that its warning label is the same as the brand name's label).

- [126](#)

[Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 37 \(1st Cir. 2012\)](#) (explaining that, unlike brand-name manufacturers, generic drug manufacturers cannot unilaterally change their labels), cert. granted, [133 S. Ct. 694 \(2012\)](#), and rev'd, [133 S. Ct. 2466 \(2013\)](#).

- [127](#)

[Id. at 30](#) (noting that Wyeth resolved the conflict against general preemption, while the Supreme Court has not extended PLIVA's exception to design-defect claims).

- [128](#)

[Id. at 37.](#)

- [129](#)

Id.

- [130](#)

[Id. at 38.](#)

- [131](#)

See [id. at 37](#) (clarifying that effective warnings and design create safe drugs, and that all companies placing a drug on the market should be held to the same standard to ensure drug safety).

- [132](#)

Id. (finding that the Wyeth rationale does not apply because generic drug manufacturers are legally prohibited from changing the label on drugs).

- [133](#)

[Id. at 38](#) (citations omitted).

- [134](#)

[Id. at 34](#) (noting that between 60-65% of the outer skin layer on Karen Bartlett's body deteriorated, was burned, or became a wound, that she spent more than fifty days in Massachusetts General Hospital's burn unit, and that she suffered from permanent near-blindness).

- [135](#)

[Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2469-70 \(2013\).](#)

- [136](#)

[Id. at 2470.](#)

- [137](#)

[Id. at 2466, 2470, 2475-76](#) (noting that the generic drug would be a different drug if it were chemically changed, and that it would need its own NDA to be marketed across state lines); cf. [Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 584 \(6th Cir. 2013\)](#) (denying impossibility preemption, as the defendant generic manufacturer could have updated its warning to match the updated warning of the brand).

- [138](#)

[Bartlett, 133 S. Ct. at 2470.](#)

- [139](#)

[Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 108 \(1992\)](#) (citations omitted) (internal quotation marks omitted).

- [140](#)

[Bartlett, 133 S. Ct. at 2473](#) (quoting [English v. Gen. Elec. Co., 496 U.S. 72, 79 \(1990\)](#)).

- [141](#)

[Id. at 2480](#) (rationalizing that Congress's intent can be inferred even without an outright expression through outlined statutory duties, and that if federal law will not allow Mutual to act in response to the demands of the state, clearly preemption was a desired consequence).

- [142](#)

[Id. at 2481-82](#) (Breyer, J., dissenting) (arguing that weight should not be given to the FDA's views on preemption because it did not hold hearings, solicit the views of the public, failed to voice its opinion through regulations, and seems to not be able to make up its mind on the issue); [id. at 2494](#) ([Sotomayor, J., dissenting](#)) (rejecting the notion that

courts are to heed an agency's conclusion about whether a state law is preempted, especially when its analysis does not satisfy the "high threshold" to determine that a state law should be preempted when faced with a conflicting federal act).

- [143](#)

Id. at 2473-77, 2479, 2480 (majority opinion).

- [144](#)

New Hampshire law recognizes liability for design-defect when "the design of the product created a defective condition unreasonably dangerous to the user ... " [Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178, 1181 \(N.H. 2001\)](#) (citation omitted). The assessment of "unreasonably dangerous" utilizes a "risk-utility" approach, wherein "a product is defective as designed if the magnitude of the danger outweighs the utility of the product." [Id. at 1182](#) (internal quotation marks omitted) (citation omitted).

- [145](#)

[Bartlett, 133 S. Ct. at 2474.](#)

- [146](#)

[Id. at 2474](#) (quoting [Vautour, 784 A.2d at 1182](#)).

- [147](#)

Id. at 2475.

- [148](#)

Id. at 2475-76 (citing [Bartlett v. Mut. Pharm. Co., 678 F. 3d 30, 41](#) (1st Cir. (2012)) (noting that a product is more dangerous if not paired with an effective warning).

- [149](#)

See id. at 2472 (citing [Bartlett v. Mut. Pharm. Co., 731 F. Supp. 2d 135, 146-47 \(D.N.H. 2010\)](#)) (highlighting the importance of changing the label in order to decrease its danger).

- [150](#)

[Bartlett v. Mut. Pharm. Co., 731 F. Supp. 2d 135, 146-47 \(D.N.H. 2010\).](#)

- [151](#)

See [Bartlett, 133 S. Ct. at 2476](#) (presenting the jury with evidence sufficient to support a finding that the drug is unreasonably dangerous).

- [152](#)

Id. (citation omitted).

- [153](#)

Id.; see also [Bartlett, 731 F. Supp. 2d at 151, 157](#) (disregarding the fact that generic companies cannot change drug labels pursuant to federal law).

- [154](#)

[Bartlett, 133 S. Ct. at 2476, 2478](#) (deciding that, like PLIVA, it is "impossible" for Mutual to satisfy state and federal labeling laws simultaneously when the only remedy is to withdraw from the market).

- [155](#)

[Id. at 2476-77](#) (quoting [Maryland v. Louisiana, 451 U.S. 725, 746 \(1981\)](#)).

- [156](#)

Id. at 2477.

- [157](#)

Id.

- [158](#)

Id. (quoting [PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2579 \(2011\)](#)).

- [159](#)

Id. at 2480, 2481 (Breyer, J., dissenting); id. at 2496 ([Sotomayor, J., dissenting](#)).

- [160](#)

Id. at 2480 (Breyer, J., dissenting).

- [161](#)

See id. at 2479 (majority opinion) (rejecting the dissent's assertion that drug companies are not legally obligated to change the Sulindac label or design, and highlighting that in terms of common law duty and statutory law, a company can either comply, leave the market, or stay in the market and suffer the consequences of non-compliance).

- [162](#)

Id. at 2480-81 (Breyer, J., dissenting) (clarifying that compliance with federal and state law is not literally impossible, but that the federal objective may be frustrated if a company can only comply by withdrawing from the market or paying a sizable fee).

- [163](#)

Id. at 2481.

- [164](#)

Id. At oral argument, Justice Kagan commented: "the adequacy of the warning is really all over this case. There was expert testimony about the adequacy of the warning, there were jury instructions about the adequacy of the warning... which does suggest that this is sort of within the four corners of Mensing." [Transcript of Oral Argument at 30-31, Bartlett, 133 S. Ct. 2466](#) (No. 12-142).

- [165](#)

[Bartlett, 133 S. Ct. at 2481](#) (Breyer, J., dissenting).

- [166](#)

Id. (noting that the FDA's views were not entitled to deference).

- [167](#)

Id.

- [168](#)

[488 U.S. 204 \(1988\)](#).

- [169](#)

[Bartlett, 133 S. Ct. at 2481](#) (Breyer, J., dissenting) (alteration in original) (citation omitted) (quoting [Bowen, 488 U.S. at 212-13](#)).

- [170](#)

Id. at 2482; see [Medtronic, Inc. v. Lohr, 518 U.S. 470 \(1996\)](#).

- [171](#)

[Bartlett, 133 S. Ct. at 2482](#) (Breyer, J., dissenting) (quoting [Wyeth v. Levine, 555 U.S. 555, 578](#)) (2009)).

- [172](#)

Id. ([Sotomayor, J.](#), dissenting).

- [173](#)

Id. at 2483.

- [174](#)

Id. at 2485.

- [175](#)
[555 U.S. 555 \(2009\).](#)

- [176](#)
[Bartlett, 133 S. Ct. at 2483-84](#) (citing [Wyeth, 555 U.S. at 581](#)) (holding that a state failure-to-warn claim regarding a brand-name drug did not warrant preemption by federal law, whereas Mutual Pharm. Co. focused on allowing generic drug preemption by federal law).

- [177](#)
Id. at 2483 (quoting [Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 \(1947\)](#)).

- [178](#)
Id.

- [179](#)
[Wyeth, 555 U.S. at 567.](#)

- [180](#)
[Bartlett, 133 S. Ct. at 2484](#) ([Sotomayor, J.](#), dissenting) (quoting Drug Amendments of 1962, [21 U.S.C. § 301](#) (2012)).

- [181](#)
[Id. at 2491-92](#) ("[Nothing in] federal law presupposes that drug manufacturers have a right to continue to sell a drug free from liability once it has been approved.").

- [182](#)
Medical Device Amendments of 1976, [21 U.S.C. § 360\(k\)](#)(2012) (including express exemption requirements for medical devices).

- [183](#)

Bartlett, 555 S. Ct. at 2485 ([Sotomayor](#), J., dissenting).

- [184](#)

Id. (quoting [Silkwood v. Kerr-McGee Corp.](#), 464 U.S. 238, 256 (1984)).

- [185](#)

Id. (quoting [Florida Lime & Avocado Growers, Inc. v. Paul](#), 373 U.S. 132, 142-43 (1963)).

- [186](#)

Id. at 2489 (noting that Mutual could have complied with state requirements while also following federal law).

- [187](#)

Id. at 2486, 2491.

- [188](#)

Id. at 2491 (quoting [Crosby v. Nat'l Foreign Trade Council](#), 530 U.S. 363, 373 (2000) (citation omitted)).

- [189](#)

See George W. Evans & Arnold I. Friede, The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis, [58 Food & Drug L.J. 365, 388 \(2003\)](#) (explaining that the main function of the FDA is to ensure that new drugs are "safe and effective for their intended uses").

- [190](#)

[Bartlett](#), 133 S. Ct. at 2485 ([Sotomayor](#), J., dissenting) (citing [Wyeth v. Levine](#), 555 U.S. 555, 574-75, 574 n.7 (2009)).

- [191](#)

See *id.* at 2491 (citing [Crosby, 530 U.S. at 373](#)).

- [192](#)

Id. at 2493.

- [193](#)

See *id.* at 2482-83 (recognizing that PLIVA expanded the scope of impossibility preemption to immunize generic drug manufacturers from state-law failure-to-warn claims).

- [194](#)

Id. at 2486.

- [195](#)

Id. at 2489 (discussing that New Hampshire did not require Mutual to do anything other than compensate consumers who were injured).

- [196](#)

Id. at 2496.

- [197](#)

Id. at 2495-96 (discussing how vaccine-related injuries were addressed largely by the states before the enactment of the National Childhood Vaccine Injury Act).

- [198](#)

See [Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1072 \(2011\)](#) (discussing the history of state run vaccine-induced injury compensation programs).

- [199](#)

[Id. at 1073.](#)

- [200](#)

Id. (discussing provisions within the National Childhood Vaccine Injury Act that establishes a no-fault compensation program, which allows a person injured by a vaccine to file a petition for compensation).

- [201](#)

[Bartlett, 133 S. Ct. at 2496 \(Sotomayor, J., dissenting\).](#)

- [202](#)

See *id.* (discussing the loss that Bartlett must bear due to preemption).

- [203](#)

See [id. at 2478](#) (majority opinion) (citing [PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 \(2011\)](#)) (explaining how the "stop-selling" argument affects the Court's rationale).

- [204](#)

[PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2580-81 \(2011\).](#)

- [205](#)

See Restatement (Third) of Torts: Products Liability § 2 (1998) (discussing product defect including defective labels); see also [Chatnam v. Pfizer, Inc., 960 F. Supp. 2d 641, 648 \(S.D. Miss. 2013\)](#) (discussing the plaintiff's claim that the drug's "defect" is in the information, which did not accompany the drug, and determining that these allegations can only relate to the drug's labeling and as such, are allegations that make up a failure-to-warn claim).

- [206](#)

[Bartlett, 133 S. Ct. at 2482 \(Sotomayor, J., dissenting\)](#) (arguing that the majority incorrectly extended its holding in *Mensing*).

- [207](#)

[Wyeth v. Levine, 555 U.S. 555, 608 \(2009\)](#) (discussing the manufacturer's continuing obligations following FDA approval of a drug).

- [208](#)

Id. at 2476-77 (discussing the majority's holding that federal law prevents generic drug manufacturers from changing their labels, and that when federal law forbids an action, the state law is preempted).

- [209](#)

Id. at 2475 (discussing the duty imposed on Mutual to strengthen labels based on the state's design-defect cause of action).

- [210](#)

Id. at 2470 (quoting [Maryland v. Louisiana, 451 U.S. 725, 746 \(1981\)](#)) (discussing the effect of the Supremacy Clause on state laws that require a private party to violate federal law).

- [211](#)

See [Bartlett v. Mut. Pharm. Co., 731 F. Supp. 2d 135, 144 \(D.N.H. 2010\)](#) (explaining that the adequacy of warnings must be judged in light of the facts at the time of injury, without the benefit of hindsight).

- [212](#)

[Bartlett, 133 S. Ct. at 2477](#) (discussing the Court of Appeals' reasoning that manufacturers could comply with federal-and state-law by stop-selling the product, which the Court found unsatisfactory); see also [PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2579 \(2011\)](#) (explaining that the Supremacy Clause does not permit an approach to preemption, such as stop-selling, that renders conflict preemption all but meaningless).

- [213](#)

At oral argument and in response to Justice Breyer, counsel for Bartlett argued that there was a distinction between adequacy of the warning (not argued) and efficacy of the

warning (argued), which minimized the risk of [Sulindac. Transcript of Oral Argument at 35-37, Bartlett, 133 S. Ct. 2466](#) (No. 12-142).

- [214](#)

[Bartlett, 133 S. Ct. at 2482](#) (Breyer, J., dissenting) (alteration in original) (quoting [Brief for Donald Kennedy & David A. Kessler as Amici Curiae Supporting Respondents, Bartlett, 133 S. Ct. 2466](#) (No. 12-142)).

- [215](#)

[Id. at 2486](#) ([Sotomayor](#), J., dissenting) (discussing the need for inquiry into congressional intent).

- [216](#)

[Id. at 2480](#) (majority opinion) (discussing the need for explicit resolution of the preemption question by Congress due to divergent views on the issue).

- [217](#)

See [555 U.S. 555, 574-75 \(2009\)](#) (discussing congressional silence on the issue of state tort law as evidence that Congress did not intend for FDA oversight to be the exclusive means of ensuring drug safety).

- [218](#)

[Bartlett, 133 S. Ct. at 2485](#) ([Sotomayor](#), J., dissenting) (second alteration in original) (quoting [Bates v. Dow Argosciences LLC, 544 U.S. 431, 451 \(2005\)](#)).

- [219](#)

See [id. at 2480](#) (majority opinion) (explaining that a lack of a preemption clause leaves the Court to discern congressional intent from the FDCA).

- [220](#)

See [id.](#) (discussing Congress' lack of activity); [id. at 2478](#) (discussing the impossibility issue).

- [221](#)

[Brief of Former FDA Commissioners Dr. Donald Kennedy and Dr. David Kellers as Amici Curiae Supporting Respondent at 8, Bartlett, 133 S. Ct. 2466](#) (No. 12-142) (discussing that FDA approval of a drug is not a guarantee that the drug will not cause serious adverse effects at a later date).

- [222](#)

Id. at 6 (discussing the indispensable role that state tort litigation plays in achieving the congressional goal of the FDCA).

- [223](#)

Id. at 12 (discussing the various conditions faced by the FDA that limit the agency's ability to singlehandedly monitor all of the drugs available on the market).

- [224](#)

[Brief for Generic Pharmaceutical Association as Amicus Curiae In Support of Petitioner at 29-31, Bartlett, 133 S. Ct. 2466](#) (No. 12-142) (discussing the negative impact that state tort laws will have on the market for manufacturing generic drugs).

- [225](#)

Id. (discussing the rise in generic drug prices as a result of state tort laws).

- [226](#)

Thomas M. Burton, FDA Rule to Expose Generic Drug Makers to Liability, Wall St. J. (July 3, 2013, 6:41 PM), http://online.wsj.com.ezproxy.library.tufts.edu/article/SB1000142412788732439940457858414_2169099794.html.

- [227](#)

Id.

- [228](#)

FDA to Allow Generic Drugmakers to Make Label Changes Independent of Innovators, Drug Industry Daily, <http://www.fdanews.com/articles/156914-fda-to-allow-generic-drugmakers-to-make-label-changes-independent-of-innovators> (last visited Nov. 13, 2014).

- [229](#)

[Brief for the United States as Amicus Curiae Supporting Petitioner at 12, Bartlett, 133 S. Ct. 2466](#) (12-142).

- [230](#)

See [Bartlett, 133 S. Ct. 2466](#) (holding that design-defect claims, like New Hampshire's, that place a duty to alter composition or labeling for safety requirements conflict with federal law, and therefore cannot stand); [Petition for Writ of Certiorari at 18, Bartlett, 133 S. Ct. 2466](#) (No. 12-142) (asserting that the Supreme Court is tasked with deciding whether precedent would be expanded to preempt state law design-defect claims); Brief of John and Tammy Gilbert et al. as Amici Curiae in [Support of Respondent at 22, Bartlett, 133 S. Ct. 2466](#) (No. 12-142) (stating that the Supreme Court has previously always held narrow circumscription of conflict preemption based on impossibility); Brief of the Council of State Governments as Amicus Curiae in [Support of Respondent at 19-20, Bartlett, 133 S. Ct. 2466](#) (No. 12-142) (noting that unlike previous decisions involving failure-to-warn claims, the present case involved the issue of whether federal law preempts design-defect claims).

- [231](#)

Brief for the United States, *supra* note 229, at 34 (quoting [Wyeth v. Levine, 555 U.S. 555, 578 \(2009\)](#)).

- [232](#)

Burton, *supra* note 226.

- [233](#)

See Toni Clark & Andrew Hay, FDA Defends Generic Drug Label Proposal at U.S. House Hearing, Reuters (April 1, 2014, 6:58 PM), <http://www.reuters.com/article/2014/04/01/genericdrugs-idUSL1N0MT11V20140401> (stating that the Supreme Court in 2011 ruled that manufacturers of generic drugs would not be liable for failure-to-warn against risk, and the FDA now would "unshackle" these manufacturers, exposing them to liability).

- [234](#)

See Kurt R. Karst, Generic Drug Labeling Preemption: The Flavor of the Day, FDA Law Blog (March 10, 2014), http://www.fdalawblog.net/fda_law_blog_hym_an_phelps/2014/03/generic-drug-labeling-preemption-the-flavor-of-the-day.html (noting that the FDA published a Preliminary Regulatory Impact Analysis addressing some cost concerns raised by lawmakers, and argued that the change would incentivize generic manufacturers to warn of safety risks).

- [235](#)

See Lisa M. Mottes, The Need For Federal Preemption of State Tort Claims in the Context of "New Drugs" and Premarket-Approved Medical Devices, [41 Seton Hall L. Rev. 723, 725 \(2011\)](#) (stating that a call for safety has been initiated as a result of these cases and Congress has indicated there should be a uniform standard of no preemption). Consider, for example, nanomedicine - the application of nanotechnology to medicine - which enables the development of drug carriers that passively target tumors and deliver and dispense chemotherapeutics for cancer treatment. See Frederick A. Fielder & Glenn H. Reynolds, Legal Problems of Nanotechnology: An Overview, 3 S. Cal. Interdisc. L.J. 593, 607-08 (1993-1994) (describing how nanotechnology-based treatments do not fit neatly into the Federal Food, Drug, and Cosmetic Act's definitions of either "drug" or "device"); see also Jennifer H. Grossman & Scott E. McNeil, Nanotechnology in Cancer Medicine, 65 Physics Today, Aug. 2012, at 38, 38 (Aug. 2012) (explaining how nanotechnology is applied to medicine to enable the development of drug carriers that passively target tumors and deliver and dispense chemotherapeutics for cancer treatment).

- [236](#)

See supra Part I.

- [237](#)

[552 U.S. 312 \(2008\)](#).

- [238](#)

Medical Device Amendments of 1976, [21 U.S.C. § 360\(k\)](#) (2012).

- [239](#)

See [Riegel, 552 U.S. at 323-24](#) (stating that federal requirements specific to a medical device preempts common-law causes of action for negligence and strict liability (citing [Medtronic, Inc. v. Lohr, 518 U.S. 470, 512 \(1996\)](#))).

- [240](#)

See [Indus. Truck. Ass'n v. Henry, 125 F.3d 1305, 1309 \(9th Cir. 1997\)](#) (explaining that in the past, federal courts have recognized three types of preemption: express, field, and conflict, the latter two categories being subcategories of implied preemption).

- [241](#)

[21 U.S.C. § 360\(k\)](#).

- [242](#)

See, e.g., [Riegel, 552 U.S. at 330](#) (holding that states are not prevented from providing a damages remedy on the basis of a violation of FDA regulations); [Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 \(1996\)](#) (holding that the MDA does not deny states the right to prove traditional damages remedy for violations of duties parallel to federal requirements); [Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 \(1997\)](#) (holding that a negligence claim for violating FDA regulations could be upheld because it did not impose greater requirements than the FDA itself imposed).

- [243](#)

See, e.g., [Talbot v. C.R. Bard, Inc., 63 F.3d 25, 28-29 \(1st Cir. 1995\)](#) (holding that the language broadly preempts any state tort law, regardless of whether the manufacturer has in fact complied with the federal standard).

- [244](#)

Federal Food, Drug, and Cosmetic Act, [21 U.S.C. §§333-335c](#) (2006) (listing penalties - criminal, civil, and regulatory - for noncompliance).

- [245](#)

Id. (including criminal, civil, and regulatory penalties, but lacking a provision for a private right of action).

- [246](#)

James W. Matthew et al., *New FDA Rule on Drug Labeling May Mean Increased Exposure and an Uncertain Path for Generic Pharmaceutical Manufacturers*, 81 *Def. Couns. J.* 306, 309 (2014) (quoting Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, [78 Fed. Reg. 67,985, 67,988-89](#) (proposed Nov. 13, 2013)) (stating that generic drug manufacturers lack incentives to comply with FDA requirements and to maintain current safety information for their products).

- [247](#)

[Riegel v. Medtronic, Inc., 552 U.S. 312, 320 \(2008\)](#) (stating that the plaintiffs, husband and wife, brought suit for injuries to the husband allegedly caused by a defective catheter).

- [248](#)

Id.

- [249](#)

[Id. at 325.](#)

- [250](#)

[Brief for Respondent at 42-43, Riegel v. Medtronic, Inc., 552 U.S. 312 \(2008\)](#) (No. 06-179) (arguing that Congress enacted a uniform federal regulatory framework to shield device manufacturers from conflicting regulatory requirements and from liability for devices that the FDA has found safe and effective).

- [251](#)

[Riegel, 552 U.S. at 325.](#)

- [252](#)

[518 U.S. 470 \(1996\).](#)

- [253](#)

[Id. at 495.](#)

- [254](#)

Id. (asserting that nothing in § 360(k) denies Florida the ability to provide a damages remedy, even if it is literally different from the federal rules, as it is not an additional or different requirement and only serves to provide more incentive to comply with federal rules).

- [255](#)

[Riegel, 552 U.S. at 323, 330.](#) See [Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 \(2001\)](#) (dismissing a state law claim for failure to make a parallel claim); [Carrelo v. Advanced Neuromodulation Sys., Inc., 777 F. Supp. 2d 303 \(D.P.R. 2011\)](#) (avoiding preemption by successfully pleading a failure-to-warn, a parallel claim); [Covert v. Stryker Corp., No. 1:08 CV447, 2009 WL 2424559, at 5 \(M.D.N.C. Aug. 5, 2009\)](#) (discussing cases upholding and denying preemption post-Riegel).

- [256](#)

[Riegel, 552 U.S. at 330](#) (holding that parallel claims cannot add to federal requirements and must be "premised" on FDA regulations).

- [257](#)

[Lohr, 518 U.S. at 508](#) (Breyer, J., concurring).

- [258](#)

[531 U.S. 341 \(2001\).](#)

- [259](#)

See *infra* Part IV.C.

- [260](#)

See supra notes 255-56 and accompanying text.

- [261](#)

See [531 U.S. at 347-48](#) (holding that state law fraud on the FDA claims were impliedly preempted by federal law).

- [262](#)

Compare [Desiano v. Warner-Lambert & Co., 467 F.3d 85, 98 \(2d Cir. 2006\)](#) (allowing parallel claims if the cause of action alleges a state claim other than fraud, by interpreting Buckman's holding to limit claims which "solely" assign liability on the basis of fraud), with [Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961, 966 \(6th Cir. 2004\)](#) (upholding implied preemption "on the basis of state court findings of fraud," but allowing the claim when a state "chooses to incorporate a federal standard into its law of torts ... when the federal agency itself determines that fraud marred the regulatory-approval process").

- [263](#)

[531 U.S. at 344.](#)

- [264](#)

Id.

- [265](#)

[Id. at 347.](#)

- [266](#)

Id.

- [267](#)

Id.

- [268](#)

[Id. at 347, 350.](#)

- [269](#)

[Id. at 349-51.](#)

- [270](#)

[Id. at 354](#) (Stevens, J., concurring).

- [271](#)

See [Stengel v. Medtronic, Inc., 704 F.3d 1224 \(9th Cir. 2013\)](#); [Hughes v. Boston Scientific Corp., 631 F.3d 762 \(5th Cir. 2011\)](#); [Bausch v. Stryker Corp., 630 F.3d 546 \(7th Cir. 2010\)](#).

- [272](#)

See *infra* Part IV.C.

- [273](#)

See *infra* text accompanying notes 297-316 (discussing cases that held that state failure-to-warn claims are preempted by federal law).

- [274](#)

See *infra* text accompanying notes 317-35 (discussing cases which narrowly interpreted *Buckman* and held that some parallel state claims are not preempted).

- [275](#)

[Easterling v. Cardiac Pacemakers, 986 F. Supp. 366, 371 \(E.D. La. 1997\)](#) (citing [Medtronic, Inc. v. Lohr, 518 U.S. 470 \(1996\)](#)).

- [276](#)

[Hinkel v. St. Jude Med., S.C., Inc., 869 F. Supp. 2d 739, 747 \(E.D. La. 2012\)](#).

- [277](#)

See *Covert v. Stryker Corp.*, No. 1:08 CV447, 2009 WL 2424559, at 5 (M.D.N.C. Aug. 5, 2009) (listing cases that have held preemption of state law claims).

- [278](#)

Compare [Stengel v. Medtronic, Inc.](#), 704 F.3d 1224, 1228-32 (9th Cir. 2013) (holding that the Lohr, Buckman, and Riegel Supreme Court decisions do not preempt parallel state claims), and [Howard v. Zimmer, Inc.](#), 711 F.3d 1148 (10th Cir. 2013) (holding that a parallel fraud claim was properly raised), and [Hughes v. Boston Scientific Corp.](#), 631 F.3d 762 (5th Cir. 2011) (reversing a lower court decision, stating that the plaintiff successfully raised a parallel fraud claim not preempted by federal law), and [Bausch v. Stryker Corp.](#), 630 F.3d 546 (7th Cir. 2010) (holding that a state action based on an alleged violation of federal law is not preempted), with [Garcia v. Wyeth-Ayerst Labs.](#), 385 F.3d 961 (6th Cir. 2004) (holding that a state fraud on the FDA cause of action was preempted).

- [279](#)

See *infra* Part IV.C.

- [280](#)

[704 F.3d 1224 \(9th Cir. 2013\).](#)

- [281](#)

[Id. at 1227.](#)

- [282](#)

Id.

- [283](#)

[Stengel v. Medtronic Inc.](#), 676 F.3d 1159, 1161 (9th Cir. 2013).

- [284](#)

[Stengel, 704 F.3d at 1227.](#)

- [285](#)

[Id.](#)

- [286](#)

[Stengel, 676 F.3d at 1161.](#)

- [287](#)

[Stengel, 704 F.3d at 1226, 1230.](#)

- [288](#)

[Id. at 1226.](#) Initially, a three-judge panel of the Ninth Circuit Court of Appeals held (2-1) for Medtronic. Stengel was then granted a rehearing en banc, in which the court reversed and remanded the decision of the three-judge panel. [Id.](#)

- [289](#)

[Stengel, 704 F.3d at 1230](#) (quoting [21 U.S.C. § 360\(k\)\(a\)\(1\)](#)).

- [290](#)

[Id. at 1226.](#)

- [291](#)

[518 U.S. 470 \(1996\).](#)

- [292](#)

See [id. at 491](#) (explaining that a sweeping preemption of "traditional" common-law remedies was not intended by the legislature).

- [293](#)

[Stengel, 704 F.3d at 123](#) (quoting [Lohr, 518 U.S. at 489](#)).

- [294](#)

[Id. at 1233-34.](#)

- [295](#)

[Id. at 1233.](#)

- [296](#)

[Id. \(quoting Lohr, 518 U.S. at 489\).](#)

- [297](#)

See [Gomez v. St. Jude Med. Daig Div. Inc., 442 F.3d 919, 932 \(5th Cir. 2006\)](#) (holding that the Louisiana statute went beyond scope of federal requirements, and related claims were preempted); [Chambers v. Osteonics Corp., 107 F.3d 1243, 1249 \(7th Cir. 1997\)](#) (holding that the Indiana negligence claim was not preempted by the MDA).

- [298](#)

[631 F.3d 762 \(5th Cir. 2011\).](#)

- [299](#)

[Id. at 771.](#)

- [300](#)

[669 F.3d 501 \(5th Cir. 2012\).](#)

- [301](#)

[Id. at 518.](#)

- [302](#)

[630 F.3d 546 \(7th Cir. 2010\).](#)

- [303](#)

[Id. at 552.](#)

- [304](#)

[718 F.3d 1209 \(10th Cir. 2013\).](#)

- [305](#)

See [Howard v. Zimmer, Inc., 299 P.3d 463, 466 \(Okla. 2013\)](#) (describing the case as involving a "long and tortured litigation trail").

- [306](#)

[Id.](#)

- [307](#)

[Id. at 465-66](#); see also [id. at 466 n.6](#) (explaining that although "Zimmer, Inc." is the defendant in the case, the name "Sulzer" was used to describe the manufacturer throughout the litigation).

- [308](#)

[Howard, 299 P.3d at 466.](#) The pre-marketing approval application for this Class III device required specific manufacturing procedures to "ensure that it is removed or limited to an amount that does not adversely affect the device's quality." [21 C.F.R. § 820.70\(h\) \(2014\)](#).

- [309](#)

[Howard, 299 P.3d at 466.](#)

- [310](#)

[Id. at 469, 472.](#)

- [311](#)

[Id. at 471-73.](#)

- [312](#)

See [Fulgenzi v. PLIVA, Inc., 711 F.3d 578 \(6th Cir. 2013\)](#) (holding that the duty-to-warn claim was not preempted); [Brooks v. Howmedica, Inc., 273 F.3d 785 \(8th Cir. 2001\)](#) (holding that the failure-to-warn and manufacturer's instructions claims were preempted); [Kemp v. Medtronic, Inc., 231 F.3d 216 \(6th Cir. 2000\)](#) (holding that negligence per se, fraud, and failure-to-warn claims were preempted).

- [313](#)

[385 F.3d 961 \(6th Cir. 2004\).](#)

- [314](#)

[Id. at 966](#); see also [Cupek v. Medtronic, Inc., 405 F.3d 421 \(6th Cir. 2005\)](#) (holding that a claim of negligence per se would be preempted under the MDA).

- [315](#)

[623 F.3d 1200 \(8th Cir. 2010\).](#)

- [316](#)

[Id. at 1205-06.](#)

- [317](#)

See [Messner v. Medtronic, Inc., 975 N.Y.S.2d 367 \(N.Y. Sup. Ct. 2013\)](#) (unpublished opinion); [Burgos v. Satiety, Inc., No. 10-CV-2680 \(MKB\), 2013 U.S. Dist. LEXIS 31062, at 1 \(E.D.N.Y., March 5, 2013\).](#)

- [318](#)

See [Perez v. Nidek Co.](#), 711 F.3d 1109 (9th Cir. 2013); [Phelps v. Wyeth, Inc.](#), 938 F. Supp. 2d 1055 (D. Or. 2013); [Elliot v. Smith & Nephew, Inc.](#), No. 112- [CV-0070-EJL-MHW](#), 2013 U.S. Dist. LEXIS 59072, at 1 (D. Idaho, June 11, 2013).

- [319](#)

See [Howard v. Zimmer, Inc.](#), 299 P.3d 463 (Okla. 2013); see also supra notes 304-11 and accompanying text.

- [320](#)

[Stengel v. Medtronic Inc.](#), 704 F.3d 1224 (9th Cir. 2013).

- [321](#)

[No. CV 12-7962 PA \(FFMx\), 2013](#) U.S. Dist. LEXIS 45852, at 1 (C.D. Cal. Mar. 25, 2013).

- [322](#)

Id. at 1-2.

- [323](#)

Id. at 6-7.

- [324](#)

Id. at 13-14.

- [325](#)

See id. at 9-10 (explaining that Stengel allows state claims that are broader than those required by FDA if those state claims are based on the defendant's failure-to-warn the FDA of the adverse health consequences of its medical device).

- [326](#)

Id. at 14, 16.

- [327](#)

[Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 353 \(2001\).](#)

- [328](#)

[Riegel v. Medtronic, Inc., 552 U.S. 312, 318 \(2008\).](#)

- [329](#)

See Jean M. Eggen, Navigating Between Scylla and Charybdis: Preemption of Medical Device "Parallel Claims", [9 J. Health & Biomed. L. 159, 184-86, 208-09 \(2013\)](#) (citing Stengel, Hughes and Bausch as examples of circuit court cases in which parallel manufacturing claims were not preempted).

- [330](#)

[625 F. Supp. 2d 769 \(D. Minn. 2009\).](#)

- [331](#)

[Id. at 777](#); see also Eggen, supra note 329, at 200 ("Some courts have correctly inferred from Lohr, Riegl, and Buckman that all properly pleaded parallel claims, other than those narrowly asserting fraud on the FDA, survive express preemption ...").

- [332](#)

[Riley, 625 F. Supp. 2d at 777.](#)

- [333](#)

Id. (citing [Buckman, 531 U.S. at 352-53](#)).

- [334](#)

Id.

- [335](#)

See Eggen, *supra* note 329, at 184-85, 208-09 (citing Hughes, Bausch, and Stengel as examples of claims that would smoothly navigate the narrow gap and survive preemption).

- [336](#)

See *id.* at 172-73, 186 (explaining that off-label use of medical devices is another area in which lower courts have inconsistently analyzed parallel claims under the preemption doctrine).

- [337](#)

[Buckman, 531 U.S. at 350.](#)

- [338](#)

See Eggen, *supra* note 329, at 210 (explaining the factors to be considered in deciding whether to preempt claims that are based on a manufacturer's misrepresentation or nondisclosure).

- [339](#)

See *id.* at 203 (explaining that preemption rules that are broadly applied would shield device manufacturers from liability, and would remove the incentive to actively engage in post-marketing vigilance).

- [340](#)

See Deena Beasley, *Medtronic Bone Graft has Limited Benefit, May Cause Harm: Reviews*, Reuters, (June 18, 2013, 3:35 AM), <http://in.reuters.com/article/2013/06/17/us-medtronic-spine-graft-idINBRE95G14Z20130617> (stating that in 2011, INFUSE, Medtronic's product, became the subject of a congressional investigation when Medtronic failed to disclose safety problems in the clinical trial data and over its off-label use).

- [341](#)

No. BC465313, 2012 WL 3876245 (Cal. Super. Ct. Aug. 20, 2012).

- [342](#)

Id.

- [343](#)

Id.

- [344](#)

United States v. Stryker Biotech LLC, Crim. No. 09-10330- [GAO, 2010 WL 2900684](#)
(D. Mass. July 21, 2010).

- [345](#)

Cabana, 2012 WL 3876245.

- [346](#)

Beasley, supra note 340.

- [347](#)

Cabana, 2012 WL 3876245.

- [348](#)

Id.

- [349](#)

Id.

- [350](#)

Beasley, supra note 340.

- [351](#)

See [Medtronic, Inc. v. Lohr](#), 518 U.S. 470 (1996); [Buckman Co. v. Plaintiffs' Legal Comm.](#), 531 U.S. 341 (2001); [Riegel v. Medtronic, Inc.](#), 552 U.S. 312 (2008).

- [352](#)

See [Wyeth v. Levine](#), 555 U.S. 555 (2009); [PLIVA, Inc. v. Mensing](#), 131 S. Ct. 2567 (2011); [Mut. Pharm. Co. v. Bartlett](#), 133 S. Ct. 2466 (2013).

- [353](#)

[Lohr](#), 518 U.S. at 495.

- [354](#)

[Buckman](#), 531 U.S. at 353.

- [355](#)

[Riegel](#), 552 U.S. at 322.

- [356](#)

[Id.](#) at 330.

- [357](#)

[630 F.2d 546](#) (7th Cir. 2010).

- [358](#)

[631 F.3d 762](#) (5th Cir. 2011).

- [359](#)

[704 F.3d 1224](#) (9th Cir. 2013) (en banc), cert. denied, [134 S. Ct. 2839](#) (2014).

- [360](#)

[Id. at 1231](#) (citing [Medtronic, Inc. v. Lohr, 518 U.S. 470, 489 \(1996\)](#)).

- [361](#)

The government's position as set forth in its amicus curiae brief arguing against the grant of certiorari is that there is no preemption by the MDA as to respondents' claims that petitioner could have advised physicians of any new safety alerts by means of a CBE revision to the product's label. See Brief for the United States as Amicus Curiae at 7, *Medtronic, Inc. v. Stengel*, 134 S. Ct. 2839 (2014) (No. 12-1351), 2014 WL 2111719, at 7.