The Mythical Failure to Update Claim

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Table of Contents

I. A Failure to Update Disqualifies a Generic Drug Manufacturer from Preemption ......................................5
II. Plaintiff Is Pursuing a Traditional State Law Failure to Warn Claim.........................................................6
   A. A Generic Drug Manufacturer Does Not Have a State-Law Duty to Provide an
      Adequate Warning.........................................................................................................................7
   B. Plaintiffs Are Trying to Privately Enforce an Alleged Violation of the FDCA.................................9
   C. There Is No State-Law Duty of Sameness .................................................................................10
III. Plaintiff Is Pursuing a Negligence Per Se Claim......................................................................................10
IV. Plaintiff Is Pursuing a Parallel Claim....................................................................................................11
V. Two Additional Reasons Why Courts Have Dismissed “Failure to Update Claims” .........................13
The Mythical Failure to Update Claim

The “failure to update” theory (including the variants of it discussed below) was concocted by plaintiffs’ attorneys in the wake of the Supreme Court’s decision in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). Approximately one month before the argument date, one of PLIVA’s attorneys sent a letter to the Supreme Court advising the Court that it had recently been brought to the attention of counsel for PLIVA that PLIVA may not have revised the labeling for its metoclopramide to include changes to the reference listed drug—Reglan”—approved by FDA on July 26, 2004.

After *Mensing*, plaintiffs seized on the “failure to update” theory, most prominently in the metoclopramide litigation, and argued the theory falls outside *Mensing* and claims based on that theory are not preempted and can proceed under state law. Courts have rejected the theory, but other courts have allowed plaintiffs to proceed based on one of more of the variations of the failure to update theory discussed below. This paper discusses the four variations of the failure to update theory, why they are not valid, and related argument points for rebutting them. Following that discussion is a discussion of two additional reasons why “failure to update claims” have been dismissed by courts.

For ease of reference, we have used the phrase “generic drug manufacturer(s)” to identify the target(s) of purported claims based on a failure to update theory.

Four variations of the Failure to Update Theory:

1. A “failure to update” disqualifies a generic drug manufacturer from preemption.
2. Plaintiff is pursuing a traditional state law failure to warn claim.
3. Plaintiff is pursuing a negligence per se claim.
4. Plaintiff is pursuing a parallel claim.

I. A Failure to Update Disqualifies a Generic Drug Manufacturer from Preemption

This theory is based on the insertion of exception into *Mensing* that does not exist. The district court in *Phelps v. Wyeth, Inc.*, 838 F. Supp. 2d 1055, 1061 (D. Or. 2013) espoused the view that “[u]nder *Mensing*, PLIVA could not be liable for failing to warn plaintiffs of the dangers of long-term metoclopramide use so long as PLIVA complied with the FDA regulations requiring a generic manufacturer to update the warning labels on its drug products to match the corresponding brand-name drug’s label.” (Emphasis supplied). Subsequently, PLIVA obtained summary judgment in *Phelps* on statute of limitations grounds. Phelps appealed to the Ninth Circuit and PLIVA cross-appealed the district court’s holding that PLIVA was disqualified from preemption. The appeal is pending.

The Oregon district court’s statement is not found in *Mensing* or supported by the language in *Mensing*. To the contrary, the majority and the dissent agreed on the breadth of the holding, *Mensing*, 131 S. Ct. at 2581 (Thomas, J., for the majority) (noting “unfortunate hand that federal drug regulation has dealt” patients taking generic drugs); *id.* at 2592 (Sotomayor, J., for dissent) (lamenting the fact that patients taking generic drugs have no right to sue):

[B]ecause pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits. ... We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.
Id. at 2581 (Thomas, J., for the majority) (internal citations omitted).

If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in Wyeth. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue.

Id. at 2592 (Sotomayor, J., for the dissenters).

As described above, when the majority and dissent wrote their opinions, the Justices were aware PLIVA may not have made a label change following the change to Reglan’s labeling in 2004. The majority did not include any “except for...” language in its opinion. The dissent, which clearly sought paths to allow a “drug consumer’s right to compensation for inadequate warnings,” did not mention an exception for consumers who received a generic drug distributed by a manufacturer that did not “update its label.” The dissenting Justices went out of their way to assert that the majority’s holding would not apply to “a situation where a brand-name manufacturer itself produces generic drug,” in which case “the manufacturer could independently change the brand-name label under the CBE regulation, triggering a corresponding change to its own generic label,” id. at 2589, fn. 12, a “situation” that was not before the Court. However, the dissenters never referenced the alleged failure to update.

Plaintiffs have argued that Mensing and Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010), which was consolidated with Mensing, did not address the failure to update theory, and events after July 26, 2004. In fact, both Ms. Mensing and Ms. Demahy were prescribed Reglan and took metoclopramide after the 2004 label change (Ms. Mensing took it through March 2005 and Ms. Demahy took it through April 2007). If a failure-to-update to include warnings approved for the RLD represented an exception to the Court’s preemption decision in Mensing, it is reasonable to conclude, given its knowledge that at least one manufacturer had not made the change, that the Court would have so stated in its decision to permit the Fifth and Eighth Circuits to apply that “exception” on remand in “further proceedings consistent with [the Court’s] opinion.” Mensing, 131 S. Ct. at 2582. Yet, it did not.

The Eighth Circuit Court of Appeals also was aware of the fact when it entered judgment for the generic drug manufacturer defendants after remand from the Supreme Court. Mensing v. Wyeth, Inc., 658 F.3d 867 (8th Cir. 2011). The same theory was presented to the Eighth Circuit in a Motion for Leave to File a Supplemental Brief. The Eighth Circuit denied the motion despite the Supreme Court’s instructions to conduct “further proceedings consistent with [the Court’s] opinion,” Mensing, 131 S. Ct. at 2582, and entered judgment affirming the dismissal of the generic drug manufacturer defendants. Mensing, 658 F.3d 867.

In short, there is no support for a construction of Mensing that the Court carved out an exception to the broad preemption articulated in Mensing if a generic drug manufacturer does not update its label after the brand-name product’s label is updated.

II. Plaintiff Is Pursuing a Traditional State Law Failure to Warn Claim

Courts that employ this fiction normally rely on Fulgenzi v. PLIVA, Inc., 711 F.3d 578 (6th Cir. 2013). See, e.g., Huck v. Wyeth, 850 N.W.2d 353 (Iowa 2014); Teva Pharmaceuticals, USA, Inc. v. Superior Court, 217 Cal. App. 4th (2013). Like the Fulgenzi panel, the courts that rely on Fulgenzi ignore the fact that another Sixth Circuit panel rejected the failure to update theory. Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011). The Fulgenzi panel declared that Smith was not binding even though the appellants in Smith asserted the same failure to update arguments (a fact the Fulgenzi panel acknowledged), and the Sixth Circuit rejected them. Inexplicably, the Fulgenzi panel refused to follow Smith based on its conclusion that “from the [Smith] opinion, it does not appear that [the arguments] were considered.” Fulgenzi, 711 F.3d at 583. That statement was demonstrably
wrong: The Smith Court's order denying rehearing en banc stated that “the issues raised in the petition [which specifically featured the “failure to update” theory of liability] were fully considered upon the original submission and decision of the cases.” Smith v. Wyeth, Inc., No. 09-5460 (6th Cir. Nov. 22, 2011) (emphasis added).

The Smith plaintiffs then filed a petition for writ of certiorari in the Supreme Court, asserting, inter alia, that their failure to update theory was not preempted, but the Supreme Court denied their writ. Smith v. Wyeth, Case No. 11-1046, 2012 WL 592900 (U.S. Apr. 30, 2012). Subsequently, another Sixth Circuit panel cast doubt on the existence of the failure to update theory. See Strayhorn v. Wyeth Pharmaceuticals, Inc., 737 F.3d 378, 399-400 (6th Cir. 2013) (“[E]ven assuming that the failure-to-update claims are not preempted under Fulgenzi, the plaintiffs have nonetheless failed to state a claim to relief that is plausible on its face” …”).

There are three related reasons why the “state-law claim” fiction is just that. First, generic drug manufacturers do not have a state-law duty to provide a warning and/or act with reasonable care with respect to the warnings in the labeling for their products. Second, a claim based on a failure to update theory is nothing more than an impermissible attempt to privately enforce the federal Food Drug and Cosmetic Act. Third, no state law imposes a duty on a generic drug manufacturer to make the labeling for its product the “same as” the labeling of the reference listed drug, and there is no corresponding state law claim for an alleged failure to match.

A. A Generic Drug Manufacturer Does Not Have a State-Law Duty to Provide an Adequate Warning

Long ago, the Supreme Court explained that the import of the Supremacy Clause's declaration that the United States Constitution, treaties, and federal statutes “shall be the supreme Law of the Land,” is that “[t]he laws of the United States are laws in the several states, and just as much binding on the citizens and courts thereof as the state laws are.” Claflin v. Houseman, 93 U.S. 130, 137 (1876). In other words, federal and state law “together form one system of jurisprudence which constitutes the law of the land for the state…” Id. The Supremacy Clause, however, mandates that federal law supersedes state law. U.S. Const. art. VI, cl. 2; see also Gade v. National Solid Wastes Management Assn., 505 U.S. 88, 108 (1992) (“[U]nder the Supremacy Clause,… any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield” (internal quotation marks omitted)). As a result, where a state law is preempted under the Supremacy Clause, only the federal law remains.

That means a generic drug manufacturer's duty is the federal duty of sameness, not the state-law duty of adequacy. The reason that is so is because in the absence of preemption, under traditional state law, a manufacturer's duty is to ensure that its product is accompanied by adequate instructions and warnings at the time the product leaves the manufacturer's control. See, e.g., Restatement (Second) of Torts, §402A; see also Mensing, 131 S. Ct. at 2577. Congress, however, when it enacted Hatch-Waxman and created the generic drug industry, imposed a duty on generic drug manufacturers to ensure their products' instructions and warnings are the “same as” those of previously-approved drugs. See 21 U.S.C. §355(j); Mensing, 131 S. Ct. at 2574 (holding generic drug must have labeling that is the same as the labeling of the brand-name drug); Mutual Pharm. Co., Inc. v Bartlett, 133 S. Ct. 2466, 2471 (2013) (same). Congress did not impose a duty on generic drug manufacturers to ensure or evaluate the adequacy of the instructions or warnings.

In other words, whether the brand-name manufacturer's warnings and instructions (and correspondingly the warnings and instructions in the labeling of generic equivalents) are adequate or inadequate is irrelevant to a generic drug manufacturer's federal duty—the generic drug manufacturer is required by federal law to copy the brand-name drug label verbatim, including text, placement, and emphasis.
In *Mensing*, the Supreme Court recognized (and in *Bartlett* reiterated) that the federal duty of “sameness” trumps the state-law duty of adequacy because federal law precludes a generic drug manufacturer from unilaterally changing its product instructions or warnings to satisfy a state-law duty of “adequacy.” See *Mensing*, 131 S. Ct. at 2578; *Bartlett*, 133 S. Ct. at 2472. The end result is that a generic drug manufacturer’s only duty then is the federal duty of “sameness” because state laws that conflict with federal law (as do state-law duties of “adequacy”) are “without effect.” *McCulloch v. Maryland*, 4 Wheat. 316, 427 (1819); see also *Atria Group v. Good*, 444 U.S. 70 (2008); *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *Hines v. Davidowitz*, 312 U.S. 52, 63 (1941). As the Court explained: “A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its label is the same as the brand’s.” *Mensing*, 131 S. Ct. at 2574 (citations omitted, emphasis added).

The *Fulgenzi* panel held the “federal duty” may inform the state-law standard of care. However, neither the *Fulgenzi* panel, nor the courts that have followed the *Fulgenzi* court have been able to articulate the state-law duty being informed. In *Fulgenzi*, PLIVA was prohibited by the federal duty of sameness from adding in its metoclopramide label the language FDA approved on July 26, 2004, before FDA approved the addition of that language to the Reglan label. PLIVAs duty to add that language in its label arose only when FDA approved the additions to the Reglan label. That conversion of a prohibition to a duty was solely a function of the federal duty of sameness. No state law duty was “informed” or came into play at all.


Generic manufacturers’ hands are tied by the FDCA in that they must use the same formulation for pharmaceuticals and conform to the name-brand labeling and no more. To measure their compliance with the law, one looks to those federal requirements, the FDA’s approvals, and the name-brand manufacturers’ actions. None of these issues requires the analysis of a duty to consumers and, in fact, a duty to consumers measured by state law requirements and what a “reasonably prudent person” would do under the same or similar circumstances may well differ from the FDAs regulatory actions. This conflict is resolved through the Supremacy Clause in favor of the federal regulatory scheme.

While [plaintiff] suggests that a “failure-to-update” claim is qualitatively different from a state law “failure-to-warn” claim, the act of “updating” cannot be measured by state law expectations but can only be governed by FDA and name-brand manufacturers’ actions and the generic manufacturer’s duty of sameness.

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The Court determines that the preemption determination with respect to the evaluation of a generic manufacturer’s duty does not depend on the particular provisions of any specific state law deemed to be in conflict. Rather, the preemption decision is based on the duty of sameness and the FDA’s regulatory scheme, which is consistent throughout the country, preempting any alternative measure of conduct. ... That is because, regardless of whether the claim is that the generic manufacturers did not comply with the duty of sameness or that they should have exceeded the minimum required by the duty of sameness, it is the duty of sameness—a federal statutory construct—that governs, rather than any alternative state law measure of adequacy of warnings.

The Garza court reversed its earlier holding that plaintiff could proceed on a failure to update claim and held the “failure-to-update claim” was barred by federal law.
B. Plaintiffs Are Trying to Privately Enforce an Alleged Violation of the FDCA

Various courts have recognized that failure to update theory is based on an alleged failure to perform a duty imposed only by the FDCA. See, e.g., Morris v. PLIVA, Inc., 713 F.3d 774, 777 (5th Cir. 2013) (holding allegation that “PLIVA breached a federal labeling obligation sounds exclusively in federal (not state) law and is preempted”); Johnson v. Teva Pharms. USA, Inc., 758 F.3d 605, 612 (5th Cir. 2014) (same); Lashley v. Pfizer, Inc., 750 F.3d 470, 475 (5th Cir. 2014) (same); Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 660 (D. Md. 2011) (denying plaintiff leave to amend claim to assert “failure-to-update” theory against PLIVA because “the weight of authority suggests that such claims are unavailing after Mensing” and stating the court is unaware of any state-law cause of action based on an alleged failure to update a generic drug’s label as required by federal law), aff’d on other grounds sub nom. Drager v. PLIVA USA, Inc., 741 F.3d 470 (4th Cir. 2014).

Congress was clear that only the federal government may bring an action to enforce the FDCA’s provisions. See 21 U.S.C. §337(a) (providing proceedings for enforcement, or to restrain violations, of FDCA “shall be by and in the name of the United States”); see also Buckman, 531 U.S. at 349 (noting “FDCA leaves no doubt it is Federal Government rather than private litigants who are authorized to file suit for noncompliance” of its provisions). See also Photomedex, Inc., v. Irwin, 601 F.3d 919, 924 (9th Cir. 2010) (“The Supreme Court made clear in Buckman that...a private plaintiff [may not] pursue claims under state-law theories where such claims collide with the exclusive enforcement power of the federal government.”).

As was true in Buckman, “the relationship between a federal agency and the entity it regulates [a generic drug manufacturer] is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.” Buckman at 347. And just as the Court in Buckman found that “the fraud claims [asserted by the plaintiff] exist[ed] solely by virtue of the FDCA disclosure requirements,” the same is true of the theory plaintiffs attempt to advance under a failure to update theory. “[T]he existence of these federal enactments is a critical element in their case.” Id. at 353. As explained Riley v. Cordis Corp., 625 F. Supp. 2d 769, 776-77 (D. Minn. 2009):

[A] private litigant cannot sue a defendant for violating the FDCA. Similarly, a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state law claim would not exist if the FDCA did not exist.

[T]he plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).

See also Cornett v. Johnson & Johnson, 48 A.3d 1041, 1054 (N.J. 2012) (“Thus, regardless of how a plaintiff styles a state claim, if the claim depends on the alleged violation of a federal requirement, it is functionally equivalent to a claim grounded solely on the federal violation, and is impliedly preempted.” (citing Buckman)).

That is why decisions from courts throughout the country are in accord with the conclusion that plaintiffs may not privately enforce alleged violations of the FDCA through theories like those plaintiffs advance here. See, e.g., Garza v. Wyeth LLC, Civ., 2015 WL 364286, *2-4 (S.D. Tex. Jan. 27, 2015) (holding “failure-to-update” theory is not based on state law and “the act of ‘updating’ cannot be measured by state law expectations but can only be governed by FDA and name-brand manufacturers’ actions and generic manufacturer’s duty of sameness”); Abicht v. PLIVA, Inc., No. 12-1278, 2013 WL 141724, *2-3 (D. Minn. Jan. 9, 2013) (rejecting plaintiffs’ “failure-to-update” theory, finding federal law is the premise of theory, and concluding “[w]here federal law supplies the duty, a state claim to enforce that duty is, in substance if not in form, a cause of action under federal law” and that federal law “precludes any private right of action for enforcement of the FDAs requirements”); Strayhorn v. Wyeth Pharms., Inc., 887 F. Supp. 2d 799, 813 (W.D. Tenn. 2012)
(“Plaintiffs’ assorted failure to conform allegations impermissibly attempt to enforce FDA regulations in violation of Buckman”), aff’d on other grounds 737 F.3d 278 (6th Cir. 2013); Bell v. PLIVA, Inc., 845 F. Supp. 2d 967, 970 (E.D. Ark. 2012) (plaintiff “does not have a federal private cause of action against PLIVA for its alleged failure to include the strengthened 2004 warning on the products dispensed to [plaintiff] in 2008”), aff’d on other grounds 716 F.3d 1087 (8th Cir. 2013); Wagner v. Pfizer, Inc., No. 13-cv-497, 2014 WL 3447476, *4 (W.D. Wis. July 11, 2014) (finding “failure-to-update” theory preempted and noting that “[t]he weight of authority is against” such a claim).

Invariably, plaintiffs pursuing a “failure to update claim” are suing because they contend the generic drug manufacturer’s actions violated the FDCA. That theory is prohibited by the FDCA and preempted. See 21 U.S.C. 337; Buckman, 531 U.S. 341. It interesting to note that the same Oregon district court which held that a failure to update claim disqualifies a generic drug manufacturer from preemption under Mensing, supra, recognized the FDCA’s prohibition on private rights of action when it denied plaintiffs’ attempt to impose liability against PLIVA for alleged misbranding and “failure to communicate drug safety information:”

When enacting the FDCA, Congress was explicit that only the federal government may bring an action to enforce its provisions. See 21 U.S.C. §337(a) (providing that proceedings for enforcement, or to restrain violations, of FDCA “shall be by and in the name of the United States”). Consequently, failure to comply with the FDCA cannot form the basis for a state-law claim. Plaintiffs cannot sue to enforce the federal statute.


C. There Is No State-Law Duty of Sameness

The same courts that have recognized the failure to update theory is based on an alleged violation of a federal law duty explicitly or implicitly also recognized there is no state law duty of sameness. Stated another way, no state law imposes a duty on a generic drug manufacturer to match the labeling of the referenced listed drug. See, e.g., Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 660 (D. Md. 2011) (denying plaintiff leave to amend claim to assert “failure-to-update” theory against PLIVA because “the weight of authority suggests that such claims are unavailing after Mensing” and stating the court is unaware of any state-law cause of action based on an alleged failure to update a generic drug’s label as required by federal law), aff’d on other grounds sub nom. Drager v. PLIVA USA, Inc., 741 F.3d 470 (4th Cir. 2014).

Those courts, like the Fulgenzi panel, that have allowed plaintiff to pursue a claim based on a failure to update theory have asserted that the lack of a state law duty of sameness “misstates” the plaintiff’s claim. Fulgenzi, 711 F.3d at 587.

III. Plaintiff Is Pursuing a Negligence Per Se Claim

Plaintiffs routinely argue they can pursue a “failure to update claim” under a negligence per se theory. The district court in Phelps agreed that plaintiffs there could pursue a negligence per se claim based on the alleged violation of the FDCA. There are a number of reasons why failure to update cannot be pursued as a negligence per se claim.

First, negligence per se concepts cannot be used to evade §337’s prohibition against private rights of action. Numerous courts have rejected attempts to do so. See, e.g., Kapps v. Biosense Webster, Inc., 813 F. Supp. 2d 1128, 1151-1152 (D. Minn. 2011) (negligence per se cannot be based on a violation of FDCA because preempted under Buckman); Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353, 1361 (N.D. Fla. 1999) (“[P]laintiff should not be able to evade the prohibition on a private right of action merely by calling his
claim for violations of the FDCA a ‘negligence per se’ claim. The substance of the claim, not the name given to it, should determine whether the claim is viable under state law”); Cali v. Danek Med., Inc., 24 F. Supp. 2d 941, 954 (W.D. Wisc. 1998) (“Under circumstances where Congress evinces no intention to create a private standard of care negligence per se cannot be based on the statute’); Alexander v. Smith & Nephew, P.L.C., 98 F. Supp. 2d 1276, 1285 (N.D. Okla. 2000) (negligence per se claim inapplicable to marketing and labeling violations under the FDCA); Talley v. Danek Med., Inc., 179 F.3d 154, 161 (4th Cir. 1999) (failure to obtain FDA approval under FDCA does not impose a standard of care or support a negligence per se claim). Those courts recognized that attempts to apply state-law negligence per se principles to alleged violations of the FDCA are merely attempted end-runs around Congress’s prohibition of private rights of action. As stated in Kemp v. Medtronic, 231 F.3d 216, 236 (6th Cir. 2000):

The determination that a violation of a federal statute such as the FDCA will create state tort liability is not a matter solely of state law. A state’s ability to use a federal statute violation as a basis for state tort liability and negligence per se depends on the intent of Congress, and not merely on the intent of the state.

Second, attempting to apply negligence per se principles is incompatible with rule that a statute may not form a basis for a civil claim where the statute does not provide for a private right of action. The desire not to circumvent legislative restrictions on the scope of causes of action via the application of negligence per se has been recognized by courts. See, e.g., Osburn v. Danek Medical, Inc., 520 S.E.2d 88 (N.C.App. 1999); Ettinger v. Denny Chanler Equip. Co., 139 Or. App. 103 (1996), rev. denied, 927 P.2d 600 (Or. 1996). The Osburn Court held that although there may be circumstances where a plaintiff may produce evidence of alleged violations to substantiate state law claims, the plaintiffs were “precluded by 21 U.S.C. §337(a) from bringing state claims ‘to redress alleged violations of the FDCA. 520 S.E.2d at 93. Similarly, in rejecting plaintiff’s argument that an alleged violation of a regulation adopted by the Oregon Department of Transportation Highway Division constituted negligence per se, the Ettinger Court noted that the state statutes and regulations in question provided only for governmental enforcement actions. Id. at 110. Where a plaintiff cannot use negligence per se to enforce a state statute that permits only governmental enforcement, surely a plaintiff cannot use negligence per se to enforce a federal statute that similarly permits only governmental enforcement.

Third, the “negligence per se doctrine does not create a new cause of action.” Talley v. Danek Medical, Inc., 179 F.3d 154, 158 (4th Cir. 1999). Nor does the doctrine create a new duty. It only “recognizes a legislatively created standard of care to be exercised where there is an underlying common-law duty.” Id. Here, there is no underlying common-law duty to update generic drug labeling. The district court in Phelps lost its way on that point as well when it held, “[b]ecause plaintiffs’ claim that PLIVA was negligent for failing to update its metoclopramide product labels in 2003 and 2004 states a viable claim under Oregon law.” 938 F.Supp. 2d at 1076. Rather than referencing a common law duty, the court relied on the duty of sameness under the FDCA and held that plaintiffs could pursue a negligence per se claim because PLIVA allegedly was negligent in discharging its federal duty. That, of course, is nothing more than saying a generic drug manufacturer can be held liable to a private citizen for violating the FDCA. A claim seeking to hold a generic drug manufacturer liable for alleged negligence in discharging its federal duty of sameness is barred by 337(a), just as a claim based on a federal duty not to commit fraud on the FDA is barred. Buckman, 531 U.S. at 353.

IV. Plaintiff Is Pursuing a Parallel Claim

Plaintiffs also routinely argue they can pursue a “failure to update claim” as a so-called parallel claim, asserting the requirement to update the label.
Those attempts to describe their purported state-law claim as one that “parallels” federal law should fail for several reasons. First, as pointed out above, there is no “parallel” state-law duty of “sameness.” Second, the parallel claim argument is nothing more than an attempt to misappropriate the concept of “parallel” claims from decisions involving express preemption provisions. Those decisions are inapplicable to the “special and different” regulations governing generic drugs, as the Fifth Circuit Court of Appeals recognized. See Lashley v. Pfizer, Inc., 750 F.3d 470, 476 (5th Cir. 2014). The Lashley Court held that the concept of “parallel” claims applies in situations where the analysis is whether a conflict exists between an express preemption provision and state law, not in those situations in which impossibility preemption under the Supremacy Clause applies. It distinguished the case before it from cases involving express preemption and medical devices, citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) and its own decision in Hughes v. Boston Scientific, 631 F.3d 762 (5th Cir. 2011), both of which are staples of plaintiffs’ parallel claim arguments.

Third, in Mensing, the Supreme Court rejected a “parallel” claim theory. Both the plaintiff and the federal government in Mensing argued that federal law did not preempt parallel claims. There, it was argued that state-law claims that paralleled the FDCAs misbranding provision were not preempted. According to the plaintiffs, the “defendants were prohibited by federal law, as by state law, from selling their products with inadequate warnings.” (Brief for Respondents, PLIVA, Inc. v. Mensing, No. 09-993, 2011 WL 686400, at *29.) Similarly, the government asserted that “[i]n addition to whatever claim [the plaintiffs’] allegations state under state law, they would also establish that [defendants’] metoclopramide products were misbranded under 21 U.S.C. §352(f) because those drugs would lack adequate warnings….” (Brief of U.S. as Amicus Curiae Supporting Respondents, PLIVA, Inc. v. Mensing, No. 09-993, 2011 WL 741927, at *30.) Mensing nonetheless held those claims preempted despite the Court’s repeated assertion that it was assuming for purposes of the decision that the plaintiffs’ state-law claims in fact paralleled the federal misbranding statute directly. See Mensing, 131 S. Ct. at 2576-78; see also id. at 2582 (Sotomayor, J., dissenting).

Plaintiffs have tried to seize upon an ambiguous footnote in Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 2566 (2013) to support an argument that the Supreme Court has recognized parallel claims against generic drug manufacturers. Bartlett was not a failure to update case. It was submitted to the Supreme Court as a design defect case. The same five justices who decided Mensing found that Bartlett’s design defect claim was preempted. The issue of whether a plaintiff can pursue a warning claim based on an alleged failure to update labeling to comply with federal law was neither presented to nor decided by the Bartlett Court.

In Footnote 4 of the Bartlett opinion, the Supreme Court wrote: “We do not address state design-defect claims that parallel the federal misbranding statute.” Plaintiffs have argued the words, “we do not address,” really mean “we are addressing” and that the language in the footnote is a “finding” by the Court. But, the Supreme Court’s words are unqualified and they plainly state the Court is not addressing either whether there is such a claim or how a claim, if it exists at all, might be adjudicated.

It also is important to bear in mind that Footnote 4 is directed specifically at a discussion in an amicus brief filed by a non-party in Bartlett, the United States Solicitor General. The discussion was about preemption of what the Solicitor General called a “pure design defect” claim—one that was not before the Supreme Court and one which the Solicitor General admitted was a theoretical design defect claim. The Solicitor General’s discussion about the theoretical claim was in the context of circumstances that would lead to withdrawal of a product from the market and included discussion of the theoretical claim against brand-name drug manufacturers, even though the manufacturer of the brand drug was not a party in Bartlett. It also is noteworthy that the phrases “parallel claim,” and “failure-to-update” do not appear anywhere in the footnote. The Sixth Circuit commented in In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation, 756 F.3d 917, 929
(6th Cir. 2014) that “academics, commentators, and even the parties to this case are not clear on what precisely Footnote 4 means and what its impact might be.”

A Georgia appellate court held that a parallel claim for misbranding can be pursued for an alleged failure to update. *Dement v. PLIVA, Inc.*, 780 S.E.2d 735 (Ga. App. 2015). The court held that plaintiff’s allegations of misbranding under the FDCA were “parallel” to her allegations of misbranding under Georgia law. *Id.* at 740. The court also held that as part of her misbranding claim, plaintiff could pursue an argument that the generic drug manufacturers should have suspended sales or withdrawn their metoclopramide products from the market. *Id.*

Of course, both “failure to update” and “misbranding” are impermissible attempts to enforce the FDCA and FDA’s regulations. Contentions that Georgia’s definition of ‘misbranding’ parallels the FDCA’s do not change the character of the claim, especially in light of the unassailable fact that neither the Georgia Drug and Cosmetic Act nor the FDCA allows private enforcement. The court of appeals in *Dement* also ignored the fact that whether a drug is “misbranded” is a determination only the FDA can make, and enforcement of alleged misbranding falls under the FDA's exclusive authority. See 21 U.S.C. §337(a) (“all…proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States”); see also *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1126 (D. Or. 2012) (addressing “misbranding” allegations as they relate to metoclopramide and explaining that “[w]hen enacting the FDCA, Congress was explicit that only the federal government may bring an action to enforce its provisions”); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab.*, 592 F. Supp. 2d 1147, 1160-63 (D. Minn. 2009) (holding there is no private right of action under the FDCA that would permit a personal injury plaintiff’s claim that the defendant “violated the FDCA by failing to inform the FDA in a timely fashion of adverse…events,” and argument for tort liability for “selling ‘misbranded’” products is preempted by 21 U.S.C. §337(a)). The FDA regulations further specifically provide that the enforcement mechanism for FDA when the labeling of a generic drug product is no longer the same as the labeling of the reference listed drug is withdrawal of approval of the ANDA for that product. See 21 C.F.R. §314.150(a)(10).

Further, plaintiff’s failure to update misbranding theory was never pled, a point the court of appeals elected to overlook. It was raised by plaintiff only in briefing and was based on the footnote from *Bartlett* discussed above that states the Court is not addressing a theoretical “pure” state-law design-defect claim (one not related to the drug’s labeling) that purportedly parallel the federal misbranding statute raised in an amicus brief. The generic drug manufacturers in *Dement* and a related case have petitioned for review by the Georgia Supreme Court.

### V. Two Additional Reasons Why Courts Have Dismissed “Failure to Update Claims”

In the Reglan/metoclopramide litigation, “the failure to update claims” have focused on a change FDA approved to the Reglan label on July 26, 2004. Subsequently in 2009, FDA instructed the NDA holder for Reglan and generic metoclopramide manufacturers to add a box warning to the labeling. Plaintiffs in the Reglan/metoclopramide litigation continued to pursue claims against manufacturer of the brand drug Reglan and claimed that all “warnings” issued before 2009, including those plaintiffs claimed generic drug manufacturers failed to timely implement after July 26, 2004, were inadequate. In other words, while plaintiffs have sought to premise their claims against generic drug manufacturers on the alleged failure to timely include the 2004 changes FDA approved for Reglan, they have alleged the labeling with those changes was inadequate.
Numerous courts have rejected the proposition that a generic drug manufacturer can be liable for providing warnings that remain inadequate and would not satisfy the state-law duty to adequately warn. The Fifth Circuit has confronted and rejected the same theory on multiple occasions, explaining that an allegation that a generic drug manufacturer failed to switch from one inadequate label to another inadequate label does not state a valid claim upon which relief can be granted. Johnson, 758 F.3d at 612 (“Tort liability does not arise for failure to attach an inadequate label.”) (quoting Morris, 713 F.3d at 777); see also Morris, 713 F.3d at 777 (“[I]t is logically incoherent to conclude that [the generic manufacturer] had a duty to apply the 2004 warning label when Appellants also assert repeatedly that no labels predating 2009 were adequate.” (second set of brackets in original). And other courts have agreed, explaining that a failure-to-update theory like plaintiffs’ cannot proceed as a matter of state law because “even if the Generic Defendants fulfilled their federal updating obligation [by updating their warnings], they would not have satisfied state law” because the warnings still would be inadequate from state law’s perspective. Bell v. Wyeth, Inc., 117 F. Supp. 3d 1355, 1364-65 (M.D. Ala. Aug. 3, 2015); see also Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 660 (D. Md. 2011), (“Plaintiff has consistently claimed that all warnings issued before 2009 relating to metoclopramide, including the brand-name warnings stating that ‘Therapy should not exceed 12 weeks in duration,’ were inadequate”), aff’d on other grounds sub nom. Drager v. PLIVA USA, Inc., 741 F.3d 470 (4th Cir. 2014).

Although other courts have focused on the fact that “failure to provide an inadequate warning claims” are barred on state law grounds because there is no state-law claim for failure to provide an inadequate warning, the court in Bell also held that such claims are barred under federal law. The Bell Court explained that plaintiff there pled the “federally compliant labeling as implemented by the Brand-Name Defendants in 2004 failed to fully comply with state law.” 117 F. Supp. 3d at 1365. The Bell Court concluded that plaintiff’s claim therefore required PLIVA to put additional warnings in the labeling in order to satisfy Alabama state law, which PLIVA could not do, and he held plaintiff’s claims are preempted.

Courts also have dismissed “failure to update claims” on the grounds that plaintiffs have not pled and/or cannot prove proximate or legal causation. Specifically, courts have held that an alleged failure to update cannot be the proximate cause of plaintiff’s injury if the prescribing physician never saw or relied upon the generic drug manufacturer’s label. Under those circumstances, any alleged shortcoming in the label could not be the proximate or legal cause of injury. Bell v. Pfizer, Inc., 716 F. 3d 1087, 1098 (8th Cir. 2013); Fulgenzi v. PLIVA, Inc., 2015 WL 6444317 (N.D. Ohio), appeal pending; see also, Pustejovsky v. PLIVA, Inc., 623 F.3d 271 (5th Cir. 2010) (affirming summary judgment for PLIVA where plaintiff’s physicians “did not recall ever reading the package insert for [metoclopramide] or consulting the Physician’s Desk Reference”); Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 112, 85 Cal. Rptr. 3d 299, 319 (2008) (holding there can be no proximate cause where the prescribing physician did not read or rely on allegedly inadequate warnings).