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File Name: 13a0065p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

ELEANOR FULGENZI,

Plaintiff-Appellant,

v.

PLIVA, INC.,

Defendant-Appellee.

No. 12-3504

Appeal from the United States District Court
for the Northern District of Ohio at Akron.
No. 5:09-cv-01767—Sara E. Lioi, District Judge.

Argued: January 16, 2013

Decided and Filed: March 13, 2013

Before: BOGGS and WHITE, Circuit Judges; and McCALLA, District Judge.[*]

COUNSEL

ARGUED: Louis M. Bograd, CENTER FOR CONSTITUTIONAL LITIGATION, P.C., Washington, D.C., for Appellant. Jeffrey F. Peck, ULMER BERNE LLP, Cincinnati, Ohio, for Appellee. **ON BRIEF:** Louis M. Bograd, CENTER FOR CONSTITUTIONAL LITIGATION, P.C., Washington, D.C., Richard W. Schulte, BEHNKE, MARTIN & SCHULTE, LLC, Vandalia, Ohio, for Appellant. Jeffrey F. Peck, Linda E. Maichl, Joseph P. Thomas, ULMER BERNE LLP, Cincinnati, Ohio, for Appellee.

OPINION

BOGGS, Circuit Judge. This case involves a state tort suit brought by Eleanor Fulgenzi against the generic-drug manufacturer PLIVA, Inc., for failure to adequately

[*]The Honorable Jon Phipps McCalla, Chief United States District Judge for the Western District of Tennessee, sitting by designation.

warn of the risks of developing tardive dyskinesia from extended treatment with metoclopramide. The question is whether the Food, Drug, and Cosmetic Act preempts such suits. In 2009, the Supreme Court held that with respect to *branded* drug manufacturers, state failure-to-warn suits were not preempted by federal law. *Wyeth v. Levine*, 555 U.S. 555 (2009). In 2011, however, the Court held that such suits could not go forward against *generic* drug manufacturers, as it is impossible for them to comply simultaneously with their state duty to adequately warn and their federal duty of sameness (federal law requires generic drug labels to be the same as their branded counterpart). *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Fulgenzi argues that her case is different: after the branded-drug manufacturer of metoclopramide strengthened the warnings on its label, PLIVA failed to update its label as required by federal law—rendering compliance with both federal and state duties no longer impossible. PLIVA argues that *Mensing* admits of no such exception, and alternatively that Fulgenzi is improperly trying to bring a state tort suit premised on violation of federal law. Fulgenzi has the stronger argument, and we reverse the decision of the district court.

I

A

For three months starting in September 2004 and for over a year from 2006 to 2007, Eleanor Fulgenzi was prescribed the generic drug metoclopramide, sold originally under the brand name Reglan, a drug approved for short-term treatment of patients suffering from gastroesophageal reflux disease. She now alleges that taking the drug caused her to develop tardive dyskinesia, an often irreversible neurological disorder that causes involuntary movements, especially of the lower face.

Metoclopramide was first approved by the Food and Drug Administration (FDA) in 1980; five years later generic manufacturers also began to produce the drug. Over time, evidence has mounted that long-term use of metoclopramide poses a substantial risk of causing tardive dyskinesia, among other serious side effects. Initially, the only disclaimer on the labeling of Reglan was: "Therapy longer than 12 weeks has not been

evaluated and cannot be recommended." In July 2004, however, the FDA approved a labeling change proposed by Schwarz Pharma, the manufacturer of Reglan, which stated in bold-face type: "**Therapy should not exceed 12 weeks in duration.**" The new warning appeared twice, as the first line in both the "Indications and Usage" and "Dosage and Administration" sections of the label. The earlier disclaimer, however, was not replaced, and remained in the dosage section for gastroesophageal reflux disease. Apparently, PLIVA never updated its metoclopramide labeling to include the new warning, nor communicated the change to any physicians. In February 2009, the FDA went further and ordered a "black-box warning"—the strongest form of warning the FDA requires—indicating the serious risk of developing tardive dyskinesia. The warning urged avoiding treatment longer than 12 weeks "in all but rare cases where therapeutic benefit is thought to outweigh the risk of tardive dyskinesia."

B

Under federal law, all prescription drugs require approval of the FDA before they can be marketed. The Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 [Hatch-Waxman Act], Pub. L. No. 98-417, 98 Stat. 1585 (1984), establishes different approval processes for branded- and generic-drug manufacturers. Branded-drug manufacturers must submit a New Drug Application (NDA) that demonstrates safety and effectiveness through clinical trials, 21 U.S.C. § 355(b), (d), and provides a label to explain the proper use and possible risks of the drug, 21 U.S.C. § 352(f)(2). Generic-drug manufacturers, in contrast, need only submit an abbreviated NDA (ANDA) to obtain approval. 21 U.S.C. § 355(j)(2)(A). An ANDA need only show that the generic drug is chemically and practically the same as its branded equivalent. In addition, the labeling must be the same as that approved for the branded drug. 21 U.S.C. § 355(j)(4)(G).

After initial approval of a drug, branded-drug companies may seek modification of their labeling[1] in two ways: first, through a "Prior Approval Supplement," which requires submission to and approval by the FDA prior to distribution of the product, and applies to most labeling and other changes with "potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product," 21 C.F.R. § 314.70(b), and second, through a "Changes Being Effected" (CBE) supplement, which must be submitted 30 days before distribution, but does not require prior FDA approval. 21 C.F.R. § 314.70(c). Label changes "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction" may be made through the CBE process. 21 C.F.R. § 314.70(c)(6)(iii)(A). Branded-drug companies, therefore, are free to update their labeling, subject only to subsequent FDA disapproval. *Wyeth*, 555 U.S. at 569.

The rules apply differently to generic-drug manufacturers. Generic-drug manufacturers must maintain labeling consistent with their branded counterpart, or else the FDA may withdraw approval. 21 C.F.R. § 314.150(b)(10). As a result, "CBE changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's." *Mensing*, 131 S. Ct. at 2575. A generic-drug manufacturer may only use the CBE process to "change[] its label to match an updated brand-name label or to follow the FDA's instructions." *Ibid*. This is the exception under which Fulgenzi argues that her claim is not preempted. Although generic-drug manufacturers cannot strengthen labels unilaterally, the FDA requires that they follow changes and strengthenings made by branded-drug manufacturers.

C

On July 30, 2009, Eleanor Fulgenzi filed suit against PLIVA, Inc., and several other pharmaceutical manufacturers, for failure to warn of the risk of developing tardive dyskinesia, among other related claims. Since all of Fulgenzi's prescriptions were filled

[1]The FDA construes "labeling" broadly, to include not just the written label associated with the drug, but communications with physicians and other healthcare professionals containing additional warnings ("Dear Doctor" letters) and information published in the *Physician's Desk Reference*. *Mensing*, 131 S. Ct. at 2576.

with generic metoclopramide, and since PLIVA was the largest generic manufacturer of metoclopramide, the district court dismissed the other manufacturers, leaving PLIVA as the sole defendant. After the Supreme Court's decision in *Mensing* narrowed the scope for state failure-to-warn claims against generic drug manufacturers, Fulgenzi was given leave to amend her complaint. In her Second Amended Complaint, Fulgenzi alleged that PLIVA's failure to include the updated 2004 warning in its labeling was in violation of its federal duty of sameness, and that failure to update "rendered its warnings inadequate under Ohio law." As Fulgenzi did not begin taking metoclopramide until September 2004, PLIVA's label was not updated the entire time Fulgenzi was prescribed the drug.

PLIVA filed a motion to dismiss, which the district court granted in March 2012. The district court reasoned that "regardless of how Plaintiff attempts to cast these claims, they are at the core, failure-to-warn claims that are clearly preempted by *Mensing*." In addition, the court found that Fulgenzi's allegations failed to state a claim under Ohio law, since there is no private cause of action for violations of FDA regulations. The district court also relied on the implicit holding of *Smith v. Wyeth*, 657 F.3d 420 (6th Cir. 2011), finding no exception to preemption for a state-law warning claim based on failure to comply with FDA regulations. Fulgenzi now appeals her product-liability claims, contesting the district court's dismissal of her allegations based on the 2004 failure to update.

II

In determining the viability of state tort claims against drug manufacturers, we are guided by two recent decisions of the Supreme Court. In a 2009 opinion authored by Justice Stevens, the Supreme Court held that failure-to-warn claims against branded-drug manufacturers were not preempted by federal law, because 1) "it is not impossible for [a branded-drug manufacturer] to comply with its state and federal law obligations" and 2) state "common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA." *Wyeth*, 555 U.S. at 581. In finding no impossibility preemption, the Court found that because the "changes being effected" (CBE) process allowed branded-drug manufacturers to strengthen warnings without prior approval of

the FDA, compliance with both federal and state duties was not impossible. *Id.* at 568. The Court did not find it significant that the FDA has authority to reject unilateral labeling changes made pursuant to the CBE process, finding it "difficult to accept" that the FDA would not have permitted a change to a stronger warning. *Id.* at 570. Without "clear evidence that the FDA would not have approved a change," the Court was unwilling to find impossibility. *Id.* at 571. The Court also denied "purposes and objectives" preemption, finding that the absence of an express preemption provision "coupled with [Congress'] certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. The Court noted that while Congress did include an express preemption provision for medical devices, 21 U.S.C. § 360k(a), no such limitation was enacted for prescription drugs. *Id.* at 574. Convinced that state-law remedies furthered Congressional consumer-protection policies, the Court rejected the argument that the FDA should be "presumed to have performed a precise balancing of risks and benefits . . . that leaves no room for different state-law judgments." *Id.* at 575.

In 2011, the Court issued another preemption decision, with Justice Thomas—who had concurred in *Wyeth*—writing the majority opinion that held failure-to-warn suits preempted against generic drug manufacturers. *Mensing*, 131 S. Ct. 2567. The Court reviewed the regulations relevant to generic drug manufacturers, finding that because generic manufacturers have a duty of sameness, they cannot use the CBE process to strengthen their labels unilaterally. *Id.* at 2575. As a result, generic manufacturers cannot independently change their drugs' safety labels. *Ibid*. In conducting its preemption analysis, the Court explained that the "question for 'impossibility' [preemption] is whether the private party could independently do under federal law what state law requires of it." *Id.* at 2579. The Court distinguished the situation in *Wyeth*, which it characterized as holding that "the possibility of *impossibility*" (i.e., possible FDA subsequent denial) was not enough for impossibility preemption, from the case at hand, which concerned "the possibility of *possibility*" (i.e., possible FDA prior approval). *Id.* at 2581 n.8. The Court did not find such conjecture

sufficient to negate impossibility. *Id.* at 2579. Summing up its analysis, the Court held that "[t]o decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 2580–81. Contrary to PLIVA's contention, the Court's decision rested squarely on this impossibility-preemption analysis and did not suggest that all suits against generic-drug manufacturers would be preempted, especially when different regulations and duties applied.

After *Mensing*, some suits against generic-drug manufacturers were summarily dismissed, while other courts permitted certain claims to go forward. *Compare Demahy v. Schwarz Pharma., Inc.*, 702 F.3d 177, 186–187 (5th Cir. 2012) (design-defect claims preempted) *and In re Darvocet, Darvon and Propoxyphene Prods. Liab. Litig.*, 2012 WL 718618, at *4 n.8 (E.D. Ky., Mar. 5, 2012) (failure-to-update claims preempted), *with Bartlett v. Mutual Pharma. Co.*, 678 F.3d 30, 37–38 (1st Cir.), *cert. granted*, 133 S. Ct. 694 (2012) (design-defect claims not preempted) *and Fisher v. Pelstring*, 817 F. Supp. 2d 791, 805 (D. S.C. 2011) (failure-to-update claims not preempted). The Sixth Circuit has dismissed one such case, explaining that "[t]he Supreme Court held unequivocally, however, that federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims." *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011). Although the *Smith* plaintiffs did raise the same arguments that Fulgenzi does here, they were raised only on supplemental briefing and, from the court's opinion, it does not appear that they were considered. As a result, we are not controlled by *Smith* and are faced with a question of first impression. Since none of the foregoing authorities are dispositive, we proceed to conduct a preemption analysis in accord with the principles of *Wyeth* and *Mensing*.

III

A

We review the question of whether a federal statute preempts state law de novo. *State Farm Bank v. Reardon*, 539 F.3d 336, 340 (6th Cir. 2008). The Supremacy Clause provides that federal law is "the supreme Law of Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. State laws, therefore, may be overridden by conflicting federal laws, both expressly and impliedly. *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 152–53 (1982). Implied preemption has been divided into "field" preemption, where "pervasive" federal regulation "preclude[s] enforcement of state laws on the same subject," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), and "conflict" preemption, which nullifies state law "to the extent that it actually conflicts with federal law," *Fidelity Fed. Sav. & Loan Ass'n*, 458 U.S. at 153. A state law actually conflicts with federal law if either 1) compliance with both is impossible, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963), or 2) the state requirement is an obstacle to "the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). In any preemption analysis, the "purpose of Congress is the ultimate touchstone," as discerned from the statutory language and structure of the statute as a whole. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485–86 (1996). Recognizing federalism concerns, courts have typically applied a presumption against preemption, especially in fields that the states have "traditionally occupied," like health and safety.[2] *Id.* at 485.

Courts will find impossibility preemption where it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). This analysis can become difficult when applied to the regulatory context—overlapping federal duties, ex-post and ex-ante agency approval,

[2]Four members of the *Mensing* majority (not joined by Justice Kennedy) cast some doubt on this presumption, arguing that the "*non obstante*" provision in the Supremacy Clause indicates that courts should not distort federal law to accommodate state law. 131 S. Ct. at 2579–80.

and ambiguous regulations make the question of whether a party is acting in accord with federal policies uncertain. In the wake of *Wyeth* and *Mensing*, however, the application of impossibility preemption principles has become clearer. *Mensing* explains that the key question is "whether the private party could independently" comply with its state duty—without relying on the prior exercise of federal-agency discretion. 131 S.Ct. at 2579, 2580–81. *Wyeth*, by contrast, holds that there is no impossibility as long as the approval comes *after* the independent action of the private party (especially where denial is speculative and unlikely). 555 U.S. at 573. In our case, not only could PLIVA have independently updated its labeling to match that of the branded manufacturer through the CBE process, *see Mensing*, 131 S. Ct. at 2575, but it had a federal duty to do so, 21 C.F.R. § 314.150(b)(10). As a result, compliance with federal and state duties was not just possible; it was required. Impossibility preemption is inappropriate in such a case. It is true that the FDA had the authority to reject PLIVA's labeling change after the fact. But this is precisely the "possibility of impossibility" that *Wyeth* found insufficient to warrant preemption. Indeed, as PLIVA had a clear federal duty to update its label, it is even less likely here that the FDA would have rejected the change. This case, therefore, presents an even weaker case for impossibility preemption than *Wyeth*.

We note at this point that Fulgenzi's claims survive only to the extent PLIVA's actions were permitted by federal law. She cannot claim that PLIVA should have included an aggressive black-box warning; any such allegations are preempted under *Mensing*. Instead, she is left to argue only that PLIVA's warning was inadequate *to the extent* that it did not include the language contained in the updated Reglan label from 2004. This leaves her with a weaker case than if she were suing a branded-drug manufacturer, but that is the statutory scheme provided to us by Congress. *See Mensing*, 131 S. Ct. at 2582.

B

We turn next to whether state tort suits against generic-drug manufacturers would frustrate the "purposes and objectives" of Congress, and thus warrant preemption. *Hines*, 312 U.S. at 67. Arguments have been made that state tort suits against generic-

drug manufacturers should be preempted by the FDCA. *See Wyeth*, 555 U.S. at 609 (Alito, J., dissenting) ("Where the FDA determines, in accordance with its statutory mandate, that a drug is on balance 'safe,' our conflict pre-emption cases prohibit any State from countermanding that determination."). The FDA must strike a balance between safety and ensuring access to life-saving drugs. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *cf. Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861 (2000). The FDA is an expert body, and better placed to set drug policy than state legislatures, much less state juries in after-the-fact verdicts. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008); *but see Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). Nevertheless, the reasoning of the *Wyeth* majority all but closes off this line of argument. *Wyeth*, 555 U.S. at 573–75, 581 ("In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling."). The Court concluded that at the time of the FDCA's passage, Congress had evidently determined that "state rights of action provided appropriate relief for injured customers." *Id.* at 574. In addition, the Court found that 70 years of Congressional failure to enact an express preemption provision for prescription drugs—despite the enactment of an express provision for medical devices—to be "powerful evidence" that Congress did not intend to preempt state remedies. *Id.* at 574–75.

One might argue that while *Wyeth*'s purposes-and-objectives analysis may control for branded drugs, the Hatch-Waxman Act sets forth different policies with respect to generic drugs. The most easily identifiable policy is promotion of generic drugs, and the attendant reduction in costs. *See* Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (July 1998) (identifying Hatch-Waxman Act as major factor in dramatic rise in sales of generic drugs and the resulting savings). Permitting state tort actions to go forward against generic-drug manufacturers, the argument goes, would increase costs and reduce usage. However, the *Mensing* dissenters plausibly observed that the inability to sue for inadequate warnings may actually reduce consumer demand. *Mensing*, 131 S. Ct. at 2593. This is an empirical question, and we should not affirmatively answer on the basis of mere speculation about Congressional purposes. *Cf.*

Wyeth, 555 U.S. at 587–88 (Thomas, J., concurring) (criticizing the "freewheeling judicial inquiry" of purposes-and-objectives preemption).

It is enough to resolve the question here that nothing in the text or structure of the Hatch-Waxman Act evidences an intent to achieve such savings at the cost of safety, effectiveness, or consumer protection. Instead, the abbreviated approval process created by the Act is premised on the duty of sameness, which ensures that generic drugs are of the same safety and effectiveness as their branded counterparts. Since 1962, the FDCA has required that all new drugs—both generic and branded—be shown safe and effective before being marketed. Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1962). The Hatch-Waxman Act did not change this requirement; it simply recognized that conducting new human clinical trials for generic drugs was "unnecessary and wasteful" where demonstrating sameness was enough to show the drug to be "safe and effective." *See* H.R. Rep. 98-857, pt. 1, at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649. The Hatch-Waxman Act's cost savings, therefore, were accomplished without comprising the FDCA's core safety policies. Here, it is uncontested that PLIVA's failure to update was in violation of its federal duty of sameness, and thus federal safety and effectiveness policies. Further, the duty of sameness does not involve the delicate balancing that other regulatory decisions (e.g., whether a life-saving but dangerous drug should be approved for marketing) require the FDA to make. It is hard to see how permitting state tort suits to go forward against sameness-violating generic defendants frustrates federal policies where permitting suits against FDA-*compliant* branded defendants does not. *Wyeth*, 555 U.S. at 573–75. A vague policy of encouraging use of generic drugs, untethered from the structure of the Act, is not enough to support purposes-and-objectives preemption. We hold therefore that state laws that provide damages for inadequate warnings in violation of the federal duty of sameness do not conflict with federal drug policy, with respect to purposes-and-objectives preemption.

IV

A

Although PLIVA's violation of its federal duty of sameness defeats its impossibility-preemption arguments, the result of this violation does raise concerns that Fulgenzi is simply attempting to enforce a federal-law violation through state litigation. Where, as here, the statute specifically excludes a private cause of action, 21 U.S.C. § 337(a), state tort suits premised on violations of federal law may be impliedly preempted, since they deprive the agency of the ability to use its enforcement authority to achieve a delicate balance of statutory objectives. *Buckman*, 531 U.S. at 348.[3] Where the claim is based on traditional state-tort-law principles, the lack of a private cause of action within a federal regulatory scheme will not preempt the claim for damages (even if state regulations might be preempted). *Silkwood*, 464 U.S. at 249. But if the claims "exist solely by virtue of" the regulatory scheme, they are preempted. *Buckman*, 531 U.S. at 353 (finding "fraud-on-the-FDA" claim preempted). If nevertheless there are independent, pre-existing state law causes of action that parallel federal safety requirements, the suit is not preempted. *Medtronic v. Lohr*, 518 U.S. at 481; *see also Riegel*, 552 U.S. at 330 ("[The express preemption provision in the Medical Device Amendments to the FDCA] does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.").[4] Here, Fulgenzi's suit is not even *premised* on violation of federal law, but rather on an independent state duty. The alleged breach arises from the same act, but the legal basis is different. This is simply not grounds for preemption. The federal duty of sameness is not "a critical element" in

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[3] *Buckman* distinguished its "fraud-on-the-agency" claim from "situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,'" which instead warrant a presumption against preemption. *Buckman*, 531 U.S. at 348. We should be cautious, therefore, in extending the reasoning of *Buckman* to claims to which the presumption applies, such as the traditional state-tort-law claims at issue here. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010).

[4] *Lohr* and *Riegel* are both express-preemption cases, dealing with the express preemption provision of the Medical Device Amendments to the FDCA. 21 U.S.C. § 360k. Here, there is no express preemption provision, so a more relaxed standard than set out in those cases is appropriate. It is unnecessary for us to define the precise contours of this standard, since Fulgenzi's claim comfortably conforms with the "parallel"-claim principle identified in *Lohr* and *Riegel*.

Fulgenzi's case. *Buckman*, 531 U.S. at 353. Failure to update from one adequate warning to another would violate the FDCA, but not Ohio law. Her suit instead relies upon the adequacy of the warnings and the causation of her injuries. The theory of her case would work equally well against a branded-drug manufacturer, or a generic-drug manufacturer whose branded counterpart had not updated its warning (of course, under *Mensing* the second case would be preempted under an impossibility theory). Fulgenzi's claim, therefore, is not preempted under *Buckman*.

B

PLIVA makes a similar argument that Fulgenzi has failed to state a claim under Ohio law, since "Ohio law does not require the manufacturer of a generic drug product to update its labeling to match the branded equivalent." Appellee Br. at 28. This misstates Fulgenzi's claim. PLIVA's violation of the federal duty of sameness is essential to her case—but only to avoid preemption under *Mensing*. On the merits, whether PLIVA has violated its federal duties is irrelevant to the adequacy of its warnings. A jury need not know about the duty of sameness at all to determine whether the warning label used by PLIVA in 2004 and 2006 was inadequate, and whether the failure to include the updated warning was a proximate cause of Fulgenzi's injuries.[5]

PLIVA also tries to argue that there is no such thing as a "failure-to-*inadequately*-warn" claim under Ohio law. Appellee Br. at 30. To start, Fulgenzi's complaint does not have to be read as asserting such a claim. While her allegation that any warning short of the FDA's 2009 "black-box" warning was unreasonable is preempted, she is free to argue in the alternative that any label lacking Reglan's 2004 updated warning was inadequate. Further, there is nothing in the Ohio product-liability law inconsistent with a claim that a defendant failed to warn, even inadequately. In a failure-to-warn case, the plaintiff must show that "[t]he manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided." Ohio Rev. Code § 2307.76. Since Fulgenzi alleges that the non-updated

[5]As will be discussed in Part IV.C *infra*, evidence of such duty might be admissible, but is not a necessary element of Fulgenzi's claim.

warning used by PLIVA in 2004 does not meet the standard of reasonable care, this element is satisfied. Fulgenzi must also demonstrate proximate causation, specifically, "whether lack of adequate warnings contributed to the plaintiff's [use of the product]." *Seley v. G. D. Searle & Co.*, 423 N.E.2d 831 (Ohio 1981). It may well be more difficult to prove proximate causation in a case where the warning that the defendant failed to provide was also legally inadequate. But there is no reason to believe that a severely inadequate warning would never cause an injury that a moderately inadequate warning would have prevented. A plaintiff need not prove that the alternative warning would have been objectively reasonable, only that it would most likely have prevented the injury in this case.

Thus Fulgenzi does not fail to properly state a claim. Fulgenzi alleges that PLIVA's use of the old warning ("Therapy longer than 12 weeks has not been evaluated and cannot be recommended.") instead of adding the updated one ("**Therapy should not exceed 12 weeks in duration.**") was unreasonable, and the proximate cause of her injuries. At the motion-to-dismiss stage, it is sufficiently plausible that the use of a neutral warning disavowing approval instead of a bold-faced warning affirmatively discouraging long-term use proximately caused Fulgenzi's injury. Whether in fact these allegations are true is a matter for further proceedings.

C

There is one final point to emphasize. Although Fulgenzi's claims are not preempted, they must pass through the "narrow gap" between *Mensing* and *Buckman*, and will be constrained as a result. *Cf. In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). The arguments she makes, the proofs she offers, and the evidence she submits are all subject to limitation by preemption principles. Under *Mensing*, Fulgenzi's claims are viable only to the extent PLIVA's actions were permitted by federal law. Thus she must argue that PLIVA should have included the language contained in the updated Reglan label by soon after July 2004, and that the failure to include that language proximately caused her injuries.

On the facts of this case, *Buckman* does not necessitate similar narrowing of Fulgenzi's claims. *Buckman* only applies where a link in the causal chain or element of the claim is premised on a federal-law violation and not in all circumstances. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (fraud exception to state-law immunity for FDA-approved drugs not preempted, as long as the FDA itself determined that fraud occurred); *see also Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (en banc) (claim premised on failure to warn the FDA not preempted). Here, as discussed *supra* Part IV.A, the federal duty of sameness is not essential to Fulgenzi's claim. Thus there is no "partial" preemption, unlike in *Mensing*.

Nevertheless, the logic of *Buckman* would encourage exclusion of evidence of federal-law violations where possible. *See Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 811–12 (N.D. Ohio 2002) (excluding evidence of fraud on the FDA if offered only to show FDA was misled, and also to prevent confusion of the jury as to the nature of the claims). Unless federal law bears on the state duty of care, evidence of such law is inadmissible. If such evidence is relevant, however, *Buckman* is no bar to its admission. Thus courts have found that, as long as authorized by state law, negligence per se suits premised on violation of federal law could go forward. *See Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 442 (6th Cir. 2010) (negligence per se claim for failure to follow federal "Good Manufacturing Practices" not preempted); *see also Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 771–72 (5th Cir. 2011) (negligence per se claim for failure to warn not preempted). Although federal-law violations here are not as relevant as they would be in a negligence per se case, references to federal law will inevitably arise. To avoid *Mensing* preemption, Fulgenzi must use the language of the 2004 FDA-approved label in her proximate-cause argument, not (or not merely) the fact of the failure to update. Federal standards are also likely to arise in determining the adequacy of PLIVA's warning, since FDA approval and industry practices may be relevant to the state duty of care.

V

For the foregoing reasons, the decision of the district court with respect to Fulgenzi's failure-to-warn claim is **REVERSED** and **REMANDED**.