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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

RITA MCDANIEL, Individually and as Personal Representative of the Estate of Johnny F. McDaniel, Deceased,

Plaintiff-Appellant,

v.

UPSHER-SMITH LABORATORIES, INC.,

Defendant-Appellee.

No. 17-5741

Appeal from the United States District Court
for the Western District of Tennessee at Memphis.
No. 2:16-cv-02604—Jon Phipps McCalla, District Judge.

Argued: April 10, 2018

Decided and Filed: June 29, 2018

Before: COLE, Chief Judge; SILER and COOK, Circuit Judges.

COUNSEL

ARGUED: Samuel C. Cole, COLE, EASLEY, SCIBA & WILLIAMS, Victoria, Texas, for Appellant. Mark C. Hegarty, SHOOK, HARDY & BACON LLP, Kansas City, Missouri, for Appellee. **ON BRIEF:** E. Kirk Wood, Jr., WOOD LAW FIRM, LLC, Birmingham, Alabama, for Appellant. Eric E. Hudson, Kyle R. Cummins, BUTLER SNOW LLP, Memphis, Tennessee, for Appellee.

COOK, J., delivered the opinion of the court in which SILER, J., joined, and COLE, C.J., joined in part. COLE, C.J. (pp. 10–13), delivered a separate opinion concurring in part and dissenting from Part II.B. of the majority opinion.

OPINION

COOK, Circuit Judge. Rita McDaniel's husband died after taking a course of a prescription drug manufactured by Upsher-Smith Laboratories, Inc. She sued, alleging that Upsher-Smith's failure to ensure that a Medication Guide accompanied the prescription led to her husband ingesting—and dying because of—a drug that wasn't meant for him. We are tasked with deciding whether the Federal Food, Drug, and Cosmetic Act ("FDCA") impliedly preempts McDaniel's Tennessee failure-to-warn claims premised solely on Upsher-Smith's failure to provide the Medication Guide as required by FDA regulations. It does. We AFFIRM.

I.

A.

We take as true the well-pleaded allegations in McDaniel's complaint and summarize them as follows. *See Stein v. HHGREGG, Inc.*, 873 F.3d 523, 528 (6th Cir. 2017).

Upsher-Smith manufactures a generic form of the prescription drug amiodarone hydrochloride ("amiodarone"). The FDA approved amiodarone in its brand-name formulation as a drug of last resort for patients suffering from ventricular fibrillation and ventricular tachycardia, both life-threatening heartbeat irregularities.

As a generic manufacturer of amiodarone, Upsher-Smith has an ongoing duty to ensure that it includes the same labeling approved for its brand-name counterpart. *See* 21 U.S.C. § 355(j)(2)(A)(v). One of those labeling requirements is to make "Medication Guides" available for distribution to each patient with each prescription, by providing them—or the means to produce them—to distributors, packers, or authorized dispensers of the drug. 21 C.F.R. § 208.24(b). Medication Guides explain the approved uses of a drug and its side effects to a patient "in nontechnical, understandable language" that is clearly presented in at least 10-point font. *See id.* § 208.20.

The Medication Guide for amiodarone warns patients that the drug "should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias." Lung damage is listed as a "serious side effect" of taking the drug, along with related symptoms such as shortness of breath and wheezing. Because "the medicine stays in your body for months after treatment is stopped," these adverse effects may continue even after ceasing treatment.

B.

Rita McDaniel, Johnny's widow, sued Upsher-Smith on behalf of her late husband's estate. In general, she alleges that her husband died in July 2015 because he had been taking amiodarone. More specifically, Johnny's doctor prescribed him a course of amiodarone to treat his non-life threatening atrial fibrillation. Johnny apparently did not receive the corresponding Medication Guide when he filled his prescriptions in May and June 2015 because Upsher-Smith neglected to ensure its availability. Thus, he was unaware that only adults with life-threatening heartbeat problems who had unsuccessfully sought alternative treatments should take the drug.

McDaniel sued on multiple theories, but only her Tennessee strict-liability failure-to-warn, negligent failure-to-warn, and negligence-per-se claims are before us. The failure-to-warn claims are premised solely on Upsher-Smith's failure to provide a Medication Guide. Upsher-Smith moved to dismiss for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). The district court granted Upsher-Smith's motion and dismissed the failure-to-warn claims with prejudice, holding that they were impliedly preempted under the FDCA. The court explained that McDaniel failed to cite any Tennessee duty paralleling the federal duty to provide a Medication Guide. Said differently, the claims would not exist in the absence of the FDCA.

II.

A.

We review de novo the district court's dismissal on federal preemption grounds. *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 583 (6th Cir. 2013).

When state and federal laws clash, federal law reigns supreme and state law is preempted. U.S. Const., art. VI, cl. 2. "State-law claims can be preempted expressly in a federal statute or

regulation, or impliedly, where congressional intent to preempt state law is inferred." *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 293 (6th Cir. 2015). In the absence of an express preemption statute, as here, federal law may impliedly preempt state law to the extent the two laws conflict. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). This type of implied preemption, known as conflict preemption, comes in two forms—impossibility and obstacle preemption. *State Farm Bank v. Reardon*, 539 F.3d 336, 342 (6th Cir. 2008). Impossibility preemption exists when compliance with both federal and state law is impossible. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963). Obstacle preemption exists when state law serves as an obstacle to the purposes and objectives embodied in a federal law. *Gade*, 505 U.S. at 98; *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

B.

McDaniel's failure-to-warn claims based on Upsher-Smith's alleged failure to provide a Medication Guide are impliedly preempted. Except in circumstances not relevant here, "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . . ." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

In alleging a failure to warn, McDaniel does not "rely[] on traditional state tort law which had predated the federal enactments in question[]. On the contrary, the existence of these federal enactments is a critical element in [her] case." *Id.* at 353. McDaniel seeks to enforce the federal regulation requiring drug manufacturers to ensure the availability of Medication Guides for distribution to patients. *See* 21 C.F.R. § 208.24. Her complaint makes this eminently clear. For instance, she asserts:

> The failure to provide each patient a "Medication Guide" by failing to provide the Medication Guides to the distributor for ultimate distribution to the patient with the drug is a direct violation of the FDA's mandate to the manufacturers of the drug intended to warn patients directly outside the communication with the prescribing physician, of the very dangers of amiodarone toxicity that injured Johnny McDaniel.

Other parts of the complaint similarly demonstrate that the existence of the Medication Guide regulation is a "critical element" in McDaniel's suit. Here are just a few:

> - The Defendant manufacturer, Upsher-Smith, was responsible by federal regulation for ensuring that the appropriate warning labels and Medication Guides were provided to McDaniel. Had the Medication Guide been provided by Upsher-Smith to the distributor or his pharmacists for distribution to him as required by FDA regulations, McDaniel . . . would not have taken amiodarone[.]
> - Because his distributors and pharmacists were not provided a Medication Guide to give directly to him outside of his doctor's office and interaction as required by FDA regulations by the Defendant manufacturer, McDaniel did not know "the medicine stays in your body for months after treatment is stopped."
> - McDaniel did not receive a Medication Guide because the Defendant Upsher-Smith did not provide the Medication Guide to the distributors for distribution to him by his pharmacists as required by the FDA and did not ensure that the Medication Guide was distributed to McDaniel.

McDaniel's opposition to Upsher-Smith's motion to dismiss further underscores that this litigation is strictly about Upsher-Smith's compliance with federal regulations that are enforceable only by the Federal Government. She insisted that her "failure-to-warn claims [are] based on Upsher-Smith's failure to provide the FDA required Medication Guide to Johnny" and that "[t]he Medication Guide that Johnny did not receive was required by federal law to be provided to" him. What's more, McDaniel explicitly disclaimed the argument that her failure-to-warn claims stem from inadequate content. She described her complaint as alleging that Upsher-Smith "failed to actually and physically provide for the appropriate distribution of federally mandated warnings in the form of the Medication Guide." Then she doubled down on her reliance on the FDA's regulations: "The allegation is not one of adequacy or 'content' failure to warn, (i.e., the verbiage or even the format fails), but an actual and physical negligent failure of Upsher-Smith to fulfill its federally mandated responsibility to ensure Medication Guides are available for distribution directly to patients with each prescription."

McDaniel cannot salvage her appeal by hanging her hat on a generic duty to warn under Tennessee law. *Cf. Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013) ("The [FDCA's] public enforcement mechanism is thwarted if savvy plaintiffs can label as

arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA."). McDaniel's failure-to-warn claims are governed by the Tennessee Products Liability Act of 1978 ("TPLA"). Tenn. Code Ann. § 29-28-102(6) (defining all actions based upon theories of strict liability or negligence as a "[p]roduct liability action" subject to the TPLA). Under the TPLA (which McDaniel neither references in her complaint nor discusses in her briefing before us or the district court), "[a] manufacturer or seller of a product in Tennessee 'shall not be liable for any injury to a person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.'" *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 392 (6th Cir. 2013) (quoting Tenn. Code Ann. § 29-28-105(a)). True, *Cansler v. Grove Manufacturing Co.* explained that, under Tennessee law, "[a] product may also be considered defective or unreasonably dangerous if the manufacturer failed to provide adequate warnings informing users of dangers involved in using the product." 826 F.2d 1507, 1510 (6th Cir. 1987). The *Cansler* plaintiff sought to show that a crane "was defective or unreasonably dangerous because the warnings concerning the dangers . . . were inadequate to apprise" him of "the nature and extent of the danger." *Id.* at 1509. But this is of no help to McDaniel, who has pleaded that the "adequacy" of warnings to her husband is not the issue; the issue is Upsher-Smith's alleged failure to ensure the Medication Guide's availability for distribution. The TPLA does not create a parallel duty to provide a Medication Guide.

McDaniel finds little support in other failure-to-warn-via-Medication-Guide caselaw. That's because the majority of the district courts to consider this very issue have found identical claims preempted. *See Moore v. Zydus Pharm. (USA), Inc.*, 277 F. Supp. 3d 873, 881 (E.D. Ky. 2017) ("Since Ms. Moore's claim concerning receipt of the medication guide exists exclusively due to the federal regulatory scheme, her claim must fail as the cause of action is merely based upon alleged violation of the FDCA . . . ."); [1] *Bean v. Upsher-Smith Pharm., Inc.*, No. 4:16-cv-01696-RBH, 2017 WL 4348330, at *6–7 (D.S.C. Sept. 29, 2017) ("Because the requirement to

[1]The *Moore* plaintiff made the same unavailing argument in opposition to that motion to dismiss as McDaniel—that "the allegation is not one of an adequacy or 'content' failure to warn . . . but an actual and physical negligent failure of Zydus to fulfill its federally-mandated responsibility to ensure that Medication Guides are available for distribution." 277 F. Supp. 3d at 880.

provide a Medication Guide to distributors is based solely in the requirements of the FDCA and related regulations, and there is no parallel duty to provide a Medication Guide under South Carolina law, Plaintiff's claims based upon failure to provide a Medication Guide are preempted under *Buckman*."), *appeal docketed*, No. 17-2263 (4th Cir. Oct. 27, 2017); *Elliott v. Sandoz, Inc.*, No. 2:16-cv-00861-RDP, 2016 WL 4398407, at *5–6 (N.D. Ala. Aug. 18, 2016) (holding "Plaintiff's claim that Defendant was negligent for failing to provide Medication Guides to Decedent is preempted by [FDCA §] 337(a)"); *Allain v. Wyeth Pharm., Inc.*, No. 2:14-cv-00280-KOB, 2015 WL 3948961, at *8–9 (N.D. Ala. June 29, 2015) (finding preempted the plaintiff's claim that defendants failed to provide Medication Guides to plaintiff's pharmacy); *see also Caughron v. Upsher-Smith Labs., Inc.*, No. 3:17-cv-21-DPM, 2017 WL 3015606, at *1 (E.D. Ark. July 5, 2017) ("Any claim based on failure to provide the medication guide to Mr. Caughron is preempted. 21 C.F.R. § 208.24(b) & (c).").[2]

The best support McDaniel marshals is *Fulgenzi v. PLIVA, Inc.* Unfortunately for McDaniel, that case does not compel us to reverse. In *Fulgenzi*, the generic-drug manufacturer PLIVA never updated its metoclopramide labeling to include the warning newly added to Schwarz Pharma's branded equivalent Reglan. 711 F.3d at 580. *Fulgenzi*'s plaintiff alleged that PLIVA's failure to update its labeling violated the federal duty of sameness required of branded- and generic-drug labeling and "rendered its warnings inadequate under Ohio law." *Id.* at 581–82. The court held that her Ohio tort claim was not preempted because "[h]er suit instead relie[d] upon the adequacy of the warnings and the causation of her injuries" instead of the "[f]ailure to update from one adequate warning to another." *Id.* at 587. Plus, "[o]n the merits, whether PLIVA ha[d] violated its federal duties [was] irrelevant to the adequacy of its warnings." *Id.*

But here, as explained above, adequacy of the warnings is not the issue. Rather, it is Upsher-Smith's alleged failure to ensure the amiodarone Medication Guide's availability for distribution—the failure to comply with a federal regulation that only the Federal Government

[2]Although the overwhelming weight of authority on this question tips the scales toward preemption, we recognize that it is not unanimous. *See, e.g.*, *Marvin v. Zydus Pharm. (USA) Inc.*, 203 F. Supp. 3d 985, 989 (W.D. Wisc. 2016) ("Plaintiffs' claim is a tort law claim based on defendant's alleged failure to warn, rather than fraud on a federal agency. Accordingly, the claim is not subject to implied preemption under *Buckman*.").

may enforce—that is the ballast steadying McDaniel's claim. In other words, whereas "[t]he federal duty of sameness [was] not 'a critical element' in Fulgenzi's case," *id.* (quoting *Buckman*, 531 U.S. at 353), the federal duty of ensuring that Medication Guides are available for distribution to a patient is the *only* element of McDaniel's failure-to-warn claims.

McDaniel insists that she, like the *Fulgenzi* plaintiff, alleged a federal-law violation strictly to avoid impossibility preemption under *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). *See Fulgenzi*, 711 F.3d at 587. We are not persuaded. In *Mensing*, patients who had taken generic metoclopramide and developed tardive dyskinesia sued the generic manufacturers for failing to update the warning labels to adequately advise of the medication's risks. 564 U.S. at 610. They claimed that state tort law obligated these manufacturers to use a stronger label. *Id.* at 617. But FDA regulations require sameness between the warning labels of a brand-name drug and its generic counterpart. *Id.* at 613; 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7). The generic manufacturers were in a bind. If they strengthened the label to satisfy state law, they'd run afoul of their federal duty of sameness; if they retained the label to satisfy federal law, they'd fall short of their state-law duty to provide adequate labeling. 564 U.S. at 618. Finding it impossible for the generic manufacturers to comply with state *and* federal law, the Supreme Court held that state law must give way and the tort claims were preempted. *Id.* at 618, 624.

This case is not like *Mensing*. There, the plaintiffs alleged that the warning labels were inadequate because they did not disclose the mounting evidence of elevated tardive dyskinesia risks associated with long-term metoclopramide use. Here, McDaniel claims that her husband did not receive the Medication Guide with his amiodarone prescription. The adequacy of warnings is not the issue—McDaniel has told us so.

And McDaniel's contention that she alleged a violation of FDA regulations only to guard against dismissal on impossibility preemption grounds is a red herring. Whereas the *Fulgenzi* plaintiff's claim of inadequate labeling did not depend on PLIVA violating its federal duties, 711 F.3d at 587, McDaniel is suing Upsher-Smith *because* its alleged conduct violates the federal Medication Guide regulations. *Cf. id.* at 588 (acknowledging that *Buckman* applies where an "element of the claim is premised on a federal-law violation"). How do we know that these FDA regulations are essential to her claims? Again, we need look no further than

McDaniel's own words: she alleges "an actual and physical negligent failure of Upsher-Smith to fulfill its federally mandated responsibility to ensure Medication Guides are available for distribution directly to patients with each prescription." We won't ignore the language of McDaniel's allegations simply so that we may shoehorn her claims into *Fulgenzi*'s realm.

So, in our words, the existence of the FDA regulations requiring a manufacturer to ensure the availability of Medication Guides for distribution to patients is critical to McDaniel's case. *See Buckman*, 531 U.S. at 353. Because McDaniel's failure-to-warn claims "would exert an extraneous pull on the scheme established by Congress," *id.*, they are therefore impliedly preempted by the FDCA, *see* 21 U.S.C. § 337(a).[3]

C.

We do not, however, address whether the FDCA impliedly preempts a claim under the doctrine of negligence per se. Under this doctrine, McDaniel seeks to rely on Upsher-Smith's violation of the Medication Guide regulations and a state misbranding statute to establish a duty of care and a breach of that duty. We conclude that McDaniel waived the right to do so under Tennessee law.

Although the negligence per se doctrine does not create a new cause of action, a plaintiff must nonetheless plead a separate claim for negligence per se under Tennessee law. *See Messer Griesheim Indus., Inc. v. Eastman Chem. Co.*, 194 S.W.3d 466, 482–83 (Tenn. Ct. App. 2005). In her complaint, McDaniel pleads a separate claim for negligence per se, but only in support of an off-label promotion claim. The district court viewed it as such in dismissing the claim, and McDaniel does not challenge the dismissal of her off-label promotion claim on appeal. Nor did McDaniel argue sufficiently in support of the doctrine in her briefing below. As we have often repeated, "an argument not raised before the district court is waived on appeal to this Court." *Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 552 (6th Cir. 2008).

III.

We AFFIRM.

[3]Because our ruling rests on preemption, we decline to address the effect of Tennessee's learned intermediary doctrine on the issues presented.

CONCURRING IN PART AND DISSENTING IN PART

COLE, Chief Judge, concurring in part and dissenting in part. We are obligated to consider the words in a complaint. At this stage, they are all that we may consider. *In re Omnicare, Inc. Sec. Litig.*, 769 F.3d 455, 466 (6th Cir. 2014). McDaniel states in her complaint that Upsher-Smith failed to provide "sufficient instructions or warnings" of the "potential risks and side effects of amiodarone" by "failing to ensure [her late husband] was timely provided the Medication Guide." Compl., R.1, ¶¶ 91, 94. In my view, these words mean what they say—that the failure to provide a medication guide rendered the warnings that were provided inadequate. The majority contends otherwise, concluding that the "adequacy of the warnings is not the issue." Maj. Op. 7. By doing so, it distinguishes *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013).

I respectfully dissent from Part II.B of the majority's opinion and conclude that we are bound by *Fulgenzi* to hold that the Food, Drug and Cosmetic Act ("FDCA") does not impliedly preempt McDaniel's Tennessee failure-to-warn claims under theories of strict liability and negligence. However, I agree with the majority that McDaniel has waived the right to rely on the doctrine of negligence per se under Tennessee law.

I.

The crux of McDaniel's Tennessee claims is straightforward: Upsher-Smith failed to provide a medication guide to her late husband, and that failure rendered inadequate the warnings of amiodarone's potential risks and side effects it did provide and caused her late husband's death.

Implied preemption leaves open a narrow gap for state failure-to-warn claims against generic drug manufacturers that resides between its two forms—impossibility and obstacle preemption. The claim must be premised on conduct that violates the FDCA to avoid impossibility preemption. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618–19 (2011). This is so because the FDCA requires a generic drug to have the same warnings as its brand-name

counterpart (under the federal duty of sameness), so that simultaneous compliance with any state duty to supply different warnings would be impossible. *Id.* At the same time, to avoid obstacle preemption, the violation of the FDCA cannot be "a critical element" of the claim. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

That narrow gap was successfully threaded in *Fulgenzi*. There, as here, the plaintiff brought a state claim against a generic drug manufacturer for its alleged failure to adequately warn of a drug's risks. *Id.* at 579–80. The claim differed only insofar as the plaintiff alleged that the failure to update the contents of the drug's labeling—and not the failure to supply a separate medication guide—rendered the warnings inadequate. *Id.* As with all failure-to-warn claims against generic drug manufacturers, the plaintiff could argue that the warnings were inadequate only to the extent that they failed to conform to the warnings provided by the brand-name manufacturer in violation of the federal duty of sameness. *Id.* at 584–85. We held that the plaintiff's claim was not preempted because the generic drug manufacturer's violation of the federal duty of sameness, although alleged in the complaint, was not a necessary (and thus not a critical) element of her claim under Ohio law. *Id.* at 581–82, 587 & n.5.

McDaniel's Tennessee failure-to-warn claims are no different. In her complaint, she alleges that Upsher-Smith violated the federal duty of sameness by failing to provide warnings in the form of a medication guide. But she cannot be faulted for doing so. The plaintiff in *Fulgenzi* made the same allegation—the only difference being the means of violating the duty. *Id.* at 581–82. And that same allegation in McDaniel's complaint is "essential to her case—but only to avoid [impossibility] preemption under *Mensing*." *Id.* at 587. That is because McDaniel must discuss federal law to show why her claims are not barred by impossibility preemption. *See Mensing* 564 U.S. at 618–19. It does not mean that she "seeks to enforce . . . federal regulation[s]." Maj. Op. 4.

McDaniel's claims are premised on a violation of an independent Tennessee duty to warn, not federal law. "The alleged breach arises from the same act"—namely, the failure to provide a medication guide. *Fulgenzi*, 711 F.3d at 587. Indeed, it must arise from the same act to avoid impossibility preemption. *See Mensing*, 564 U.S. at 618–19. "[B]ut the legal basis is different." *Fulgenzi*, 711 F.3d at 587. McDaniel's claims depend on whether the warnings

provided were inadequate and proximately caused her late husband's death. *See id.* at 587; *Barnes v. Kerr Corp.*, 418 F.3d 583, 590 (6th Cir. 2005) (listing elements of Tennessee failure-to-warn claims). Because the fact of a federal-law violation is not a necessary element of those claims, they are not subject to obstacle preemption under *Buckman*. *Fulgenzi*, 711 F.3d at 587 & n.5.

When faced with an apparent conflict between the words in a complaint and a brief responding to a motion to dismiss, we are obligated to choose the former. It is, after all, the sufficiency of the allegations in the complaint that we are evaluating. *See* Fed. R. Civ. P. 12(b)(6). The majority focuses on a singular remark in McDaniel's briefing that "[t]he allegation is not one of adequacy or 'content' failure to warn, (i.e., the verbiage or even the format fails), but an actual and physical negligent failure of Upsher-Smith to fulfill its federally mandated responsibility to ensure Medications Guides [sic] are available for distribution directly to patients with each prescription." R. 23, PageID 111. The majority interprets that statement to mean that, unlike in *Fulgenzi*, McDaniel "pleaded that the 'adequacy' of warnings . . . is not the issue." Maj. Op. 6.

The complaint tells us that McDaniel pleaded precisely the opposite: "The warnings and directions provided with amiodarone by [Upsher-Smith] failed adequately to warn of the potential risks and side effects of amiodarone." Compl., R. 1, ¶¶ 91, 98. And context tells us that the purported concession in the brief was meant to explain why the claim is not barred by impossibility preemption—clarifying in the same section that what she meant is that she "does not allege that the contents of the labeling should have been changed" in violation of the federal duty of sameness, only that a separate "Medication Guide and its warnings were not provided to him in accordance" with that duty. R. 23, PageID 113. Indeed, it necessarily follows that McDaniel's claims challenge the adequacy of the warnings that were provided, alleging as they do that a death would not have occurred but for the failure to provide additional warnings in the form of a medication guide.

II.

Tennessee's learned intermediary doctrine does not bar McDaniel's claims. Under this doctrine, Upsher-Smith argues that its duty to warn under Tennessee law extended only to her husband's prescribing physician. And this would mean that McDaniel's claims are barred, either because (1) there is no Tennessee duty paralleling the federal duty to provide a medication guide, or (2) she fails to allege that the prescribing physician was inadequately warned.

Upsher-Smith cannot dispense with its duty to warn McDaniel's late husband of amiodarone's risks. Under Tennessee law, the learned intermediary doctrine "constitutes a defense," rather than a common-law rule delineating to whom a manufacturer owes the duty to warn. *See Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 701 (Tenn. 2011). When the defense is invoked, "a pharmaceutical manufacturer can discharge its duty to warn by providing the physician with adequate warnings of the drug's risks." *Id.* This defense, however, does not eliminate Upsher-Smith's "continuing duty to warn the users" of its prescription drugs. *See Payne v. Novartis Pharm. Corp.*, 767 F.3d 526, 530 (6th Cir. 2014) (interpreting Tennessee law). Adequately warning a physician is simply one means of discharging that duty.

Dismissal under this defense would be premature at this juncture. A plaintiff is not required to plead around all potential defenses. *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004). Only when a plaintiff "admits all the ingredients of an impenetrable defense" may a complaint that otherwise states a claim be dismissed. *Id.* As Upsher-Smith points out, McDaniel does not allege that her husband's physician was unaware of the risk of lung damage associated with amiodarone. But she also does not allege that his physician was aware of that risk. Discovery is the proper vehicle to explore those factual issues.

At this stage, it is enough that McDaniel has pleaded a plausible claim to relief that is neither precluded by the learned intermediary doctrine nor preempted by the FDCA.