APPENDIX

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[ENTERED: June 29, 2018]

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File Name: 18a0128p.06

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 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

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[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.

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 may enforce—that is the

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[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*.").

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.

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[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.

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Jun 29, 2018
DEBORAH S. HUNT, Clerk

No. 17-5741

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

Plaintiff - Appellant,

v.

UPSHER-SMITH LABORATORIES, INC.,

Defendant - Appellee.

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

JUDGMENT

On Appeal from the United States District Court for the Western District of Tennessee at Memphis.

THIS CAUSE was heard on the record from the district court and was argued by counsel.

IN CONSIDERATION THEREOF, it is ORDERED that the judgment of the district court is AFFIRMED.

ENTERED BY ORDER OF THE COURT

/s/
Deborah S. Hunt, Clerk

[ENTERED: May 25, 2017]

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

RITA McDANIEL, Individually and as Personal Representative of the Estate of JOHNNY F. McDANIEL, Deceased,	
Plaintiff,	No. 2:16-cv-02604-JPM-cgc
v.	
UPSHER-SMITH PHARMACEUTICALS, INC.,	
Defendant.	

ORDER GRANTING DEFENDANT'S MOTION TO DISMISS

Before the Court is Defendant Upsher-Smith Pharmaceuticals, Inc.'s Motion to Dismiss the Amended Complaint, filed February 17, 2017. (ECF No. 29.) For the reasons stated below, the Motion to Dismiss is GRANTED.

I. BACKGROUND

A. Factual Background

Rita McDaniel brings an action on behalf of the estate of Johnny F. McDaniel for wrongful death. Plaintiff asserts that her husband was prescribed 200 mg amiodarone tablets in May 2015 for treatment of his non-life-threatening atrial fibrillation. (ECF No. 26 at PageID 221.) The amiodarone tablets were manufactured and sold by Upsher-Smith Pharmaceuticals, Inc as a generic version of Wyeth's Cordarone under the name Paecerone. (Id. at PageID 222; ECF No. 29-1.) Wyeth has received approval from the Food and Drug Administration (FDA) to market and sell amiodarone as a drug of last resort for patients suffering from life-threatening ventricular fibrillation and ventricular tachycardia. (ECF No. 26 at PageID 214; ECF No. 29-1 at PageID 290.) Plaintiff asserts that Defendant promoted the "off-label" use of amiodarine as an initial treatment for patients with atrial fibrillation, though Defendant was aware that such a use had not received FDA approval and may result in serious pulmonary illness, toxicity, and death. (ECF No. 26 at PageIDs 214-215.) Plaintiff asserts that her husband was given the amiodarone for off-label use, though he was not in a situation of "last resort" as to the management of his atrial fibrillation and his condition was not life threatening. (Id. at PageIDs 215, 221.) Mr. McDaniel received his medication at the Naval Branch Health Clinic. (Id. at PageID 221.) Plaintiff further asserts that Mr. McDaniel did not receive the FDA Medication Guide and current warning labels for the prescriptions. (Id.) Plaintiff

alleges that Mr. McDaniel developed several pulmonary complications as a result of the inappropriate off-label use. (Id. at PageID 225.) Mr. McDaniel was admitted to Methodist LeBonheur Hospital on June 22, 2015 and died on July 22, 2015 at the age of 78. (Id. at PageIDs 215, 225.) Plaintiff asserts six claims: (1) strict liability/failure to warn, (2) negligence – failure to warn, (3) negligence – marketing and sales, (4) negligence per se, (5) fraud and deceit, and (6) wrongful death. (Id. at PageIDs 236-48.)

B. Procedural Background

Plaintiff filed a Complaint on July 21, 2016. (ECF No. 1.) Defendant filed a Motion to Dismiss on August 22, 2016. (ECF No. 17.) On January 26, 2017, the Court entered an order granting in part and denying in part Defendant's Motion to Dismiss, granting Defendant's motion as to Counts I-IV of the Complaint, denying Defendant's motion as to Count VI of the Complaint (wrongful death), and granting Plaintiff leave to amend Count V of the Complaint (fraud and deceit). (ECF No. 25.) Plaintiff filed an Amended Complaint on February 6, 2017. (ECF No. 26.) In the Amended Complaint, Plaintiff includes the dismissed Counts I-IV "to preserve the issue[s] for appeal," amends Count V (fraud and deceit), and preserves Count VI (wrongful death). (Id.) Plaintiff filed a Motion for Certificate of Appealability on February 6, 2017, which the Court denied on April 5, 2017. (ECF Nos. 28, 31.) Defendant filed a Motion to Dismiss the Amended Complaint on February 17, 2017. (ECF No. 29.) Due to Plaintiff's failure to respond to the motion to dismiss, the Court entered an Order to Show Cause on April 5, 2017. (ECF No.

31.) Plaintiff responded to the Order to Show Cause on April 19, 2017, stating that "Plaintiff opposes that Motion to Dismiss but stands on the content and allegations of the Amended Complaint filed in accordance with the Court's Order." (ECF No. 33.)

II. Legal Standards

A. Motion to Dismiss

A court may dismiss a claim for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

> A complaint must contain a short and plain statement of the claim showing that the pleader is entitled to relief. . . . A claim is facially plausible when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. . . . [T]he court need not accept as true allegations that are conclusory or require unwarranted inferences based on the alleged facts.

Newberry v. Silverman, 789 F.3d 636, 640 (6th Cir. 2015) (citations and internal quotation marks omitted). "Plausibility is not the same as probability, but it requires 'more than a sheer possibility that a defendant has acted unlawfully.'"

Mik v. Fed. Home Loan Mortg. Corp., 743 F.3d 149, 157 (6th Cir. 2014) (quoting Iqbal, 556 U.S. at 678). A court must "construe[] the complaint in a light most favorable to the plaintiff." HDC, LLC v. City of Ann Arbor, 675 F.3d 608, 611 (6th Cir. 2012).

B. Fraud Claims

In alleging fraud by misrepresentation, Federal Rule of Civil Procedure 9(b) requires a plaintiff to plead with particularity "the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." Fed. R. Civ. P. 9(b); Sanderson v. HCA-The Healthcare Co., 447 F.3d 873, 877 (6th Cir. 2006) (quoting Yuhasz, 341 F.3d 559, 563 (6th Cir. 2003)); Glassner v. R.J. Reynolds Tobacco Co., 223 F.3d 343, 346 (6th Cir. 2000) ("[A] complaint alleging fraud must allege with particularity those circumstances constituting fraud"). Rule 9(b) requires a plaintiff "(1) to specify the allegedly fraudulent statements; (2) to identify the speaker; (3) to plead when and where the statements were made; and (4) to explain what made the statements fraudulent." Republic Bank & Trust Co. v. Bear Stearns & Co., Inc., 683 F.3d 239 (6th Cir. 2012). At a minimum, a plaintiff must "allege the time, place and contents of the misrepresentation(s) upon which he relied." Bender v. Southland Corp., 749 F.2d 1205 (6th Cir. 1984). The "conditions of a person's mind may be alleged generally," but "the plaintiff still must plead facts about the defendant's mental state, which, accepted as true, make the state-of- mind allocation 'plausible on its face.'" Republic, 683 F.3d at 247.

A claim of fraud by omission, in so far as it relates to failure to comply with a disclosure requirement set forth by FDA regulations, is expressly preempted under the FDCA. Hafer v. Medtronic, Inc., 99 F.Supp.3d 844 (W.D. Tenn. 2015). (See also ECF No. 25 at PageIDs 201-03, 206-07 (summarizing case law to explain that a claim based on the failure to provide a medication guide in accordance with FDCA requirements is preempted by federal law).)

C. Wrongful Death Claims

Tennessee's wrongful death statute, Tennessee Code Annotated § 20-5-106(a), does not create a new, independent cause of action for surviving beneficiaries. Lynn v. City of Jackson, 63 S.W.3d 332, 335 (Tenn. 2001); Ki v. State, 78 S.W.3d 876 (Tenn. 2002) ("Beneficiaries do not have an individual claim or cause of action for the wrongful death of the decedent."). "Tennessee's wrongful death statute is a 'survival' statute – it preserves only the decedent's cause of action." Johnson v. Memphis Light Gas & Water Division, 777 F.3d 838 (6th Cir. 2015). "The decedent's survivors are only asserting the decedent's right of action on behalf of the decedent." Ki, 78 S.W.3d at 880. Beneficiaries may only "recover damages for their individual losses that arise pursuant to the right of action vested in the decedent." Id.

III. Analysis

Defendant argues that the two remaining counts in the Amended Complaint must be dismissed for failure to state a claim. (ECF No. 29-1.)

Specifically, Defendant asserts that Plaintiff's claim of fraud and deceit in Count V still fails to satisfy the pleading standards of Federal Rule of Civil Procedure 9(b). (Id. at PageIDs 292-96.) Defendant also argues that Plaintiff's claim of wrongful death fails as a matter of law because the underlying theories of liability are without merit. (Id. at PageIDs 296-99.)

A. Fraud and Deceit

Count V of Plaintiff's Amended Complaint (fraud and deceit) alleges that that Defendant misled Mr. McDaniel, his physician, scientific and medical communities, the FDA, and the public regarding the safety risks of amiodarone. (ECF No. 26 at PageID 242-48.) In the Amended Complaint, Plaintiff adds additional language specifying that Defendant acted fraudulently by failing to provide the Medication Guide to Mr. McDaniel and putting forth affirmative misrepresentations while marketing amiodarone on its website and distribution centers. (Compare id. with ECF No. 1 at PageIDs 32-35.) Defendant argues that Plaintiff "has not pleaded any new facts to cure her deficient complaint." (ECF No. 29-1 at PageID 293.) Defendant additionally argues that Plaintiff's amended Count V fails to state a claim because "it merely re-alleges that Upsher-Smith failed to distribute a Medication Guide for amiodarone, a claim the Court dismissed as preempted." (Id. at PageID 295.)

The Court agrees with Defendant that Plaintiff's Amended Complaint fails to plead fraud by misrepresentation with the particularity required by Federal Rule of Civil Procedure 9(b). The

Amended Complaint does not identify the time, place, or content of the alleged misrepresentations. Plaintiff merely states that Defendant continue to market amiodarone on its website and distribution centers, but does not specify the time period in which amiodarone was marketed, the web address the misrepresentations allegedly made at the distribution centers. Plaintiff has not specified any fraudulent statements, identified any speakers of such statements, or pled when and where the statements were made.

The additional language included in Count V of the Amended Complaint largely consists of allegations that Defendant acted with fraud and deceit by failing to provide the Medication Guide to Mr. McDaniel. These allegations appear to plead a claim of fraud by omission. Though Plaintiff's claim of fraud by omission is pled with greater particularity, any allegations regarding Defendant's failure to provide a Medication Guide are federally preempted as the Court discussed in its previous order. (See ECF No. 25 at PageIDs 206-07.) The Court therefore grants Defendant's Motion to Dismiss with regard to Count V.

B. Wrongful Death

In the Amended Complaint, Plaintiff maintains her claim against Defendant for wrongful death, alleging that the death of Johnny McDaniel was caused by Defendant's negligence (Count VI). (ECF No. 26 at PageID 248.) Defendant argues that, "because all of Plaintiff's underlying theories of liability have been dismissed or are without merit,

Plaintiff's purported cause of action for wrongful death also fails." (ECF No. 29-1 at PageID 296.)

Tennessee's wrongful death statute does not create a new cause of action for surviving beneficiaries; rather, it merely preserves the decedent's claims. Plaintiff cannot assert a sole cause of action for wrongful death and all of the other causes of action in the Amended Complaint have been dismissed. As a result, Defendant's Motion to Dismiss is granted with regards to Count VI of the Complaint.

IV. CONCLUSION

For the reasons stated above, Defendant's Motion to Dismiss (ECF No. 29) is GRANTED. All claims asserted by Plaintiff against Defendant are dismissed with prejudice.

IT IS SO ORDERED, this 25th day of May, 2017.

/s/ Jon P. McCalla
JON P. McCALLA
UNITED STATES DISTRICT JUDGE

[ENTERED: May 25, 2017]

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

RITA McDANIEL, Individually and as Personal Representative of the Estate of JOHNNY F. McDANIEL, Deceased,	
Plaintiff,	No. 2:16-cv-02604-JPM-cgc
v.	
UPSHER-SMITH PHARMACEUTICALS, INC.,	
Defendant.	

JUDGMENT

JUDGMENT BY COURT. This action having come before the Court on Defendant's Motion to Dismiss the Amended Complaint, filed on February 17, 2017 (ECF No. 29), and the Court having entered an Order Granting the Motion to Dismiss (ECF No. 34),

IT IS THEREFORE ORDERED, ADJUDGED, AND DECREED that, in accordance with the Order Granting the Motion to Dismiss (ECF No. 34), all

claims by Plaintiff against Defendant are hereby DISMISSED with prejudice.

APPROVED:

/s/ Jon P. McCalla
JON P. McCALLA
UNITED STATES DISTRICT JUDGE

May 25, 2017
Date

[ENTERED: August 2, 2018]

No. 17-5741

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Aug 02, 2018
DEBORAH S. HUNT, Clerk

RITA McDANIEL, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF JOHNNY F. McDANIEL, DECEASED,	)	
Plaintiff-Appellant,	)	
v.	)	ORDER
UPSHER-SMITH LABORATORIES, INC.,	)	
Defendant-Appellee.	)	

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

The court received a petition for rehearing en banc. The original panel has reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. The petition then was circulated to the full court. No judge has requested a vote on the suggestion for rehearing en banc.

Therefore, the petition is denied.

ENTERED BY ORDER OF THE COURT

/s/

Deborah S. Hunt, Clerk

[ENTERED: February 6, 2017]

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE

RITA McDANIEL, Individually and as Personal Representative of the Estate of JOHNNY F. McDANIEL, Deceased, Plaintiff,	)	
vs.	)	Civil Action No.: 2:16-cv-02604-JPM
UPSHER-SMITH PHARMACEUTICALS, INC. Defendants.	)	

AMENDED COMPLAINT

Comes Now RITA McDANIEL, individually and as Personal Representative of the Estate of JOHNNY F. McDANIEL, Deceased, herein referred to as Plaintiffs, in the above numbered and styled case, files this First Amended Complaint against UPSHER-SMITH PHARMACEUTICALS, INC. (hereinafter "Upsher-Smith" or "Defendant") for cause of action will show to the Court as follows:

I. Introduction & Nature of Action

1. JOHNNY F. McDANIEL, (hereinafter "Johnny" or "McDaniel" or "Plaintiff's Decendent") is an individual who resided in Cordova, Shelby County, Tennessee before his untimely death on July 22, 2015. This cause of action is duly brought on behalf of the estate of JOHNNY F. McDANIEL by

the Personal Representative of the estate, RITA McDANIEL (hereinafter "Rita" or "Rita McDaniel" or "Plaintiff"). Rita McDaniel resides in Cordova, Shelby County, Tennessee. Johnny McDaniel was prescribed, purchased, and ingested the drug amiodarone (described more fully herein), which was manufactured, promoted and/or sold or distributed by Defendant and as a proximate cause thereof, Johnny McDaniel suffered severe and debilitating injury to his pulmonary system resulting in his slow and painful death. Johnny McDaniel died as a result of taking the drug, and his personal representative files this amended complaint as a result of Defendant's wrongful conduct.

2. Johnny McDaniel suffered from severe pulmonary problems and death as the direct result of consuming a product, amiodarone, which was manufactured, promoted, supplied, sold, and distributed by the Defendant.

3. Amiodarone is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, manufactured and distributed by the Defendant. Prescription, medical records and the NDC Number of the tablets prescribed and ingested by Johnny McDaniel all confirm McDaniel consumed amiodarone; more particularly the amiodarone manufactured by Upsher-Smith, actively promoted for "off-label" use by Upsher-Smith and provided to McDaniel without the mandated Mediation Guide.

4. Johnny McDaniel was diagnosed with atrial fibrillation.

5. Defendant's scheme involved and continues to involve a calculated and deceitful sales

and promotional campaign to include paid physician to physician interactions specifically designed to be seen as unbiased information, and an equally egregious failure and refusal to take required, timely, and accurate corrective actions and notice to medical professionals and consumers to prevent catastrophic injury and death to its customers, such as Johnny McDaniel. Defendant Upsher-Smith additionally benefited from the scheme and continues to do so and supports the scheme by the continued sale of amiodarone for "off-label" use by atrial fibrillation patients such as McDaniel.

6. Defendants, like many other drug companies, have spent and spends millions of dollars each year to persuade doctors to prescribe their particular drugs. More particularly, Defendants spent time and money promoting the use of amiodarone "off-label" for patients with atrial fibrillation such as McDaniel. There are, however, strict FDA regulations about the form and content of such promotion. In fact, it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug. Defendant, by various sales efforts, continued to promote the sale of amiodarone without concern for unapproved uses and more particularly concern for patients with atrial fibrillation. Defendants' scheme of promoting the use of amiodarone for "off-label" atrial fibrillation has been so pervasive and insidious so as to wrongfully influence medical professionals.

7. The purpose of the federal regulations[1] and requirements governing prescription drugs is to

[1] 21 U.S.C. §§ 331(d), 352(f), and 355.

protect patients by ensuring drug manufacturers subject prospective uses of their drugs to randomized and well-controlled clinical trials. The purpose of such trials is to determine whether the drug is safe and effective for such uses, at least when sufficient promise lies to make the cost of such randomized trials worth incurring. These requirements are meant to ensure that drug companies like the Defendants, give physicians and medical personnel trustworthy unbiased information to use in making prescribing decisions, so that medications are prescribed and branded appropriately and with adequate and up to date warnings.

8. A manufacturer's duty to test a use arises, under both common law and federal law, particularly when the manufacturers learn of any adverse events concerning its sale.

9. As described in further detail herein, in 1985, the initial manufacturer and distributor in the United States or "brand" manufacturer, Wyeth, received FDA approval to market and sell amiodarone only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only such use when these conditions would not respond to other available anti-arrhythmic drugs and therapies.[2]

10. Defendant was aware that Wyeth hired agents and embarked on a course of conduct, the purpose of which was to increase amiodarone sales as an initial, first-line anti-arrhythmic medication, a

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[2] *See* NDA 18-972, Approval Letter, December 24, 1985.

use for which amiodarone has never received FDA approval; i.e., an "off-label" use.

11. Defendant knew of the extreme dangers and catastrophic injuries and death caused by amiodarone, known through adverse events reporting, customer and physician communications, and other sources, which existed for years, when the Defendant entered the market with amiodarone products.

12. Upon information and belief, Defendant recognized a significant profit potential in the dangerous "off-label" promotion and sale of amiodarone as a first-choice cardiac drug for non-life threatening heart ailments; particularly atrial fibrillation, a much more common non-life threatening illness impacting millions of individuals.

13. The Defendant tracked and had full knowledge of the number of prescriptions written for amiodarone to be given as a first-line cardiac drug, and has, through various means, designed to conceal their involvement, promoted and conspired together and with others to promote the use of amiodarone as an initial, first-line therapy for all arrhythmias and other heart ailments.

14. Defendant's scheme was implemented and enabled Defendant to eventually tap into the enormous market for amiodarone in the United States.

15. Upon information and belief, and at all material times hereto, Defendant was aware from multiple sources, that many of Defendant's amiodarone prescriptions were, and are currently, written for "off-label" purposes, i.e., for the purpose of controlling non-life threatening atrial fibrillation.

16. Defendant's scheme, described in more detail below, ultimately deceived physicians, pharmacists, distributors and consumers into believing that prescribing and taking amiodarone for the "off-label" atrial fibrillation uses that Defendant promoted was appropriate even though Defendant knew FDA approval had not been granted for those uses and, moreover, there was significant medical-scientific evidence indicating amiodarone was very dangerous in those situations, and in fact, resulted in serious pulmonary illness and toxicity, and death, when so used.

II. Parties

17. At the time of his death, July 22, 2015, Johnny McDaniel was retired. Johnny McDaniel was a 78-year-old resident of Cordova in Shelby County, Tennessee. Mr. McDaniel died at Methodist LeBonheur Hospital in Germantown, Tennessee on July 22, 2015.

18. Plaintiff Rita McDaniel is an adult individual and resident of Cordova, Shelby County, Tennessee. Rita McDaniel is the widow of Johnny McDaniel and Personal Representative of the Estate of Johnny F. McDaniel.

19. Defendant Upsher-Smith Pharmaceuticals, Inc. is a Minnesota corporation with its principal place of business in Maple Grove, Minnesota. Defendant Upsher-Smith regularly conducts business in Tennessee and throughout the United States and is involved in the manufacture, distribution, marketing, sale, labeling, and design of amiodarone in the State of Tennessee and throughout the United States as detailed below.

20. The Defendant conducts substantial, systematic continuous, and regular business in Tennessee, as well as throughout the United States and is involved in the distribution, marketing, sale, labeling, and design, of amiodarone in the State of Tennessee and throughout the United States as detailed below.

21. At all material times, upon information and belief, Defendant authorized and/or acted by and through its officers, employees, agents, servants, and/or representatives, including those actively engaged in the legal defense of Defendant.

22. At all material times, every reference made to any corporate Defendant in this Amended Complaint includes predecessors, successors, parents, subsidiary, affiliates, and divisions of the corporation for the corresponding time period.

23. Whenever reference is made to any act, deed, or transaction of Defendant, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or representatives while they were actively engaged in the corporation's management, direction, control, or business affairs. Any Defendant that is a subsidiary of a foreign parent acted as its parent company's agent for its parent's U.S. sales.

III. Jurisdiction and Venue

24. Venue is proper pursuant to §28 U.S.C. §81 and §91 because a substantial part of the events or omissions giving rise to the claim occurred within the District of Tennessee. The injuries at issue in

this lawsuit occurred in the District of Tennessee and the Plaintiff's decedent was a citizen of the State of Tennessee.

25. Defendants conduct business in the District of Tennessee. Defendant's commercial activities in the District of Tennessee include, but are not limited to, the marketing, sale and distribution of amiodarone and other pharmaceuticals.

IV. Factual Background

26. All prescription drugs require approval by the Food and Drug Administration (hereinafter "FDA") before the drug may be marketed. Manufacturers of new drugs must submit a new drug application (hereinafter "NDA") to the FDA. An NDA must include information about the drug's safety and efficiency gleaned from clinical trials.[3] It must also propose a label reflecting appropriate use, warnings, precautions, and adverse reactions.[4]

27. For generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the Food, Drug, and Cosmetic Act (hereinafter "FDCA") and is referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an "abbreviated new drug application" (hereinafter "ANDA") procedure for generic manufacturers.[5] Generic manufacturers are not required to repeat the clinical trials conducted by name brand manufacturers. ANDA's are approved

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[3] 21 U.S.C. § 355(a)-(b).

[4] 21 C.F.R. § 201.56

[5] 21 U.S.C. § 355(j).

based on the initial safety profile of the name brand drug and are subject to all post-marketing events and post-sales events, including, but not limited to, collecting, tracking, and reporting adverse incident reports regarding the drug.

28. In 1985, brand manufacturer Wyeth received FDA approval[6] to market and sell the anti-arrhythmic heart medication Cordarone® (amiodarone hydrochloride is the generic formulation) under a special "needs" approval without the usually mandated rigorous and FDA approved, double-blind, randomized clinical trials. Although the FDA has urged Wyeth to conduct randomized clinical trials, such trials have not been conducted. The FDA approval for Cordarone® remains a special and unusual "special needs" approval. The customary and rigorous randomized clinical trials now required by the FDA for all new drug applications have never been conducted for amiodarone. Wyeth was the initial manufacturer, promoter and distributor or "brand manufacturer" of Cordarone® in the United States.

29. Wyeth's Cordarone® was approved only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Wyeth aggressively and successfully marketed Cordarone® for inappropriate "off-label" uses as a "first line anti-arrhythmic therapy."

30. Wyeth also instituted and maintained an active promotional campaign to physicians

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[6] *See* NDA 18-972, Approval Letter, December 24, 1985.

touting the anti-arrhythmic benefits of amiodarone; a campaign from which generic manufacturers such as Defendants still benefit. The campaigns focused on the use of the drug for atrial fibrillation and failed to warn prescribing physicians of the potential dangers associated with amiodarone toxicity and dangers to atrial fibrillation patients. Wyeth's campaigns were pervasive and effective. The drug wrongfully became a first line therapy for atrial fibrillation because physicians were not warned of many of the potential dangers of the drug. In fact the brand manufacturer, Wyeth's fraudulent and misleading marketing campaigns resulted in warning letters from the FDA to stop the false and misleading promotion of the drug that downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy.[7] The FDA letters noted that it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug.[8] The purpose of this federal requirement is to protect patients by ensuring drug manufacturers subject prospective uses of their drugs to randomize and well-controlled clinical trials to determine whether the drug is safe and effective for such uses. These requirements are meant to ensure that drug companies like Defendant, would give physicians and medical personnel trustworthy information so that medications are prescribed appropriately. Physicians may still prescribe drugs for unapproved uses. These unapproved uses are deemed "off-label" because they have not been

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[7] Warnings by the FDA to Wyeth began as early as 1988. http://www.mcclatchydc.com/2003/11/04/28118/fda-oversight-of-off-label-drug.html

[8] *See* 21 U.S.C. §§ 331(d), 352(f), and 355

approved by the FDA. (A pharmaceutical company is permitted to disseminate certain information about "off-label" uses, but such dissemination must adhere to strict requirements. For instance, the manufacturer must submit an application to the FDA seeking approval of the drug for "off-label" use; the manufacturer must provide its marketing materials to the FDA prior to dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically sound information . . . necessary to provide objectivity and balance."[9]) The dissemination of information in violation of these provisions violates the Food, Drug and Cosmetic Act (hereinafter "FDC Act").[10] This law also requires pharmaceutical companies to furnish federal regulators with advance copies of any and all information they disseminate.[11] Any deviation from these requirements violates FDA regulations.

31. The brand manufacturer Wyeth received approval for the manufacture, marketing, sale and distribution of the generic formulation amiodarone hydrochloride in 1998.[12] As with all generic bioequivalent approvals, Defendant Upsher-Smith was required by the FDA to provide patients prescribed the drug with all FDA approved labels,

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[9] 21 U.S.C. § 360aaa, *et seq*

[10] 21 U.S.C. § 331(z)

[11] 21 U.S.C. § 360aaa

[12] The approval letter noted on the FDA database is addressed to Copley Pharmaceutical, Inc. and dated November 30, 1998. http://www.accessdata.fda.gov/drugsatfda_docs/anda/98/74-739_Amiodarone_Approv.pdf

warnings and medication guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.[13] Defendant took advantage of the pervasive brand innovator promotional activities of Wyeth and Defendant's versions of the drug directly benefited from the decades of marketing of the drug for "off-label" uses by Wyeth. The version of the drugs produced by Defendant was also subject to the same advertising, marketing, and promotional requirements and restrictions set forth by the FDA for Wyeth in their advertising, marketing, and promotion of the drug Cordarone®. Defendant was required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings, and medication guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.[14] In fact, the FDA letter to Wyeth, of which Defendant was well aware, also specifically referenced the on-going review and approval of any and all promotional materials for the drug as well as addressed the monitoring and reporting requirements of the manufacturer.[15]

32. As with all generic bioequivalent approvals, Defendant was required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand

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[13] *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

[14] *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

[15] *See* Application 75-188 Approval Letter to Robert A. Fermia dated February 24, 1999.

formulation manufacturer, Wyeth, and as updated as directed by the FDA.[16] Defendant took advantage of the pervasive promotional activities of Wyeth. Defendant's generic version of the drug directly benefited from the marketing of the drug for "off-label" uses by Wyeth as well as its own promotional activities.[17]

33. Prior to being prescribed amiodarone, Johnny McDaniel was diagnosed with atrial fibrillation that was not deemed life threatening. Johnny McDaniel was not in a medical situation of "last resort" as to the management of his atrial fibrillation.

34. Beginning in May of 2015 and continuing on through June of 2015, and as a result of the continuing sales efforts of Defendant, Dr. James Litzow prescribed McDaniel a course of 200 mg amiodarone tablets for treatment of his non-life threatening atrial fibrillation. McDaniel filled the prescription and ingested the drug amiodarone according to the instructions.[18] Johnny McDaniel was not aware that his use of the medication was for an "off- label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. More importantly, McDaniel did not receive the required Medication Guide from Defendant for the prescriptions he filled at the Naval Branch Health Clinic. McDaniel did not receive the Medication Guide from his pharmacist because the Defendant

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[16] *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).

[17] *See* Application 75-188 Approval Letter to Robert A. Fermia dated February 24,1999.

[18] Naval Branch Health Clinic

did not provide Medication Guides to the distributors and pharmacists for distribution to McDaniel with his prescription. Because he did not receive the Medication Guide, McDaniel received and ingested a mislabeled drug. Correction of atrial fibrillation and any use accept in situations of last resort were never FDA approved uses of Cordarone® or its generic equivalents. McDaniel's prescription was for an "off-label" use and without the benefit of the FDA mandated Medication Guide. McDaniel was unaware of the dangers he faced from the drug that caused his injuries.

35. The prescription for the amiodarone tablets McDaniel received were identified as tablets manufactured, marketed and distributed by Upsher-Smith Pharmaceuticals, Inc. The amiodarone ingested by McDaniel was the generic version of Wyeth's Cordarone®. This "off-label" prescription and distribution of the drug to control a non-life threatening atrial fibrillation, also a direct result of the long term promotional efforts of Defendants and without the required Medication Guide, was a producing and proximate cause of Johnny McDaniel's physical condition and injuries from amiodarone toxicity.

36. McDaniel was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. More importantly, he did not receive the key warning information in the required Medication Guide from Defendant for the prescriptions he filled at the pharmacies.

37. McDaniel was not provided the Medication Guide[19] or the appropriate and up to date warning labels from Defendant that were required to be given directly to McDaniel outside of his interaction with Dr. Litzow to warn him of the serious and life threatening side effects of amiodarone. 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 have been aware of the serious lung related side effects that would lead to his physical condition and injuries as well as other issues. McDaniel would not have taken amiodarone and would not have incurred the serious and life threatening injuries had he received the required Medication Guide.

38. The serious side effects outlined in the Medication Guide, all of which McDaniel experienced after taking amiodarone, included lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression.[20]

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[19] The FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that certain information is necessary to prevent serious adverse effects; patient decision- making should be informed by information about a known serious side effect with a product, or patient adherence to directions for the use of a product are essential to its effectiveness. http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

[20] Medication Guide for amiodarone HCI. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf

39. Because his distributors and pharmacists were not provided a Medication Guide to provide to him with his prescriptions by the Defendant manufacturer, McDaniel did not know that amiodarone "should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias" and even then when "other treatments did not work or were not tolerated."[21] He did not know that any other use such as the use for his atrial fibrillation was considered to be "off-label" and McDaniel did not know of the corresponding dangers associated with such uses.

40. 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."[22] The effects of amiodarone are extremely long lasting. Amiodarone is fat-soluble, and tends to concentrate in tissues including fat, muscle, liver, lungs, and skin and confers a high volume of distribution and a long half-life; the amount of time it takes for one-half of an administered drug to be lost through biological processes (metabolism and elimination). Because of this long half-life, amiodarone's dangerous properties continue to cause injuries in patients such as McDaniel long after he ceased using the drug, including, serious pulmonary injuries. This information was unknown to McDaniel

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[21] Medication Guide for amiodarone HCI. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf

[22] Medication Guide for amiodarone HCI. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf

due to the failure of the Defendant manufacturer to provide the Medication Guide to the distributors.

41. Each manufacturer who ships a container of an FDA approved drug product for which a Medication Guide is required is responsible for ensuring that Medication Guides are available for distribution directly to patients with each prescription.[23] Defendant Upsher-Smith is a manufacturer as defined by the FDA and is required to provide the Medication Guides to the distributors so that the distributors can provide the Medication Guides to pharmacists who then can provide the Medication Guides directly to the patient. The FDA has recognized that "it is important that patients receive appropriate risk information in the form of Medication Guides in order to make informed decisions about certain prescribed medications." The Medication Guides are to specifically provide information directly to the patient outside of the interaction with the physician. It is important to note that the FDA has mandated that the warnings included in the Medication Guides go directly to the distributor and via the distributor and pharmacists directly to the patient as an important notification distributed outside and in addition to any warning or information that is provided by the physician. Drugs identified by the FDA for the Medication Guide procedure are significantly dangerous to such a degree that the FDA requires a warning outside of information provided directly by the physician. The FDA has expressed concern at the failure of drug manufacturers in the distribution of the Medication Guides to the distributors and that "the current

[23] *See* 21 CFR § 208.24

Medication Guide program is too cumbersome and that it lacks a standard distribution system." Failure to provide the Medication Guide results in the distribution of a mislabeled and illegal drug.

42. The National Consumer Pharmacy Association has also identified the failure of manufacturers to ensure the distribution of Medication Guides to distributors and thus to the patients as a significant safety issue and called on the FDA to "enforce current FDA MedGuide regulations holding manufacturers accountable for providing Medication Guides in sufficient number or the means to produce Medication Guides in sufficient number, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product."[24] McDaniel did not receive a Medication Guide because the Defendant Upsher-Smith did not provide the required 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.

43. In the spring of 2015, McDaniel began to experience many of the symptoms outlined in the Medication Guide to include shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression.

44. McDaniel's condition continued to deteriorate. He experienced increasing pulmonary issues to include shortening of breath, deep cough

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[24] Use of Medication Guides to Distribute Drug Risk Information to Patients, Colleen Brennan, RPh; Bryan Ziegler, PharmD, MBA

and difficulty in doing the active life that he always enjoyed.

45. McDaniel was admitted to Methodist LeBonheur Hospital on June 22, 2015 with severe shortness of breath and remained in the hospital until his death on July 22, 2015.

46. At all material times, amiodarone caused and contribute to severe and disabling medical conditions and death, such as those experienced by Johnny F. McDaniel, including, without limitation, the following: pulmonary toxicity, pulmonary fibrosis, hepatic damage and failure, neurotoxicity, neonatal hypothyroidism, birth defects, optic neuritis, toxic optic neuropathy, blindness, peripheral neuropathy, heart damage and failure, hypotension, serious exacerbation of arrhythmias, and congestive heart failure.

47. Upon information and belief, Defendant, has received information concerning deaths and serious injury resulting from the use of amiodarone.

48. Upon information and belief, Defendant has received information concerning cases of severe medical conditions resulting from the use of amiodarone, including, without limitation, pulmonary toxicity, pulmonary fibrosis, lung damage, hepatic damage and failure, neurotoxicity, peripheral neuropathy, neonatal hypothyroidism, optic neuritis, toxic optic neuropathy, blindness, serious exacerbation of arrhythmias, and congestive heart failure such as that experienced by Johnny McDaniel.

49. Healthcare providers, as well as patient-consumers reported these events, upon information and belief, directly to the company.

50. In addition to these direct notices of adverse events, the FDA had, and continues to have, in effect, an adverse reaction surveillance system for all regulated drugs, including amiodarone, called the Adverse Event Reporting System (AERS).

51. Upon information and belief, the AERS has placed Defendant on notice of numerous instances of catastrophic injuries caused by ingestion of amiodarone.

52. At all material times, Defendant failed to disclose to the FDA, healthcare professionals, consumers, or McDaniel, of the information they possessed concerning the incidents and actual adverse medical events, injuries, and deaths suffered by amiodarone users. Instead, upon information and belief, the Defendant actively took advantage of the promotional efforts of innovator brand drug manufacturer Wyeth, for "off-label," unapproved uses as described herein through various means as well as its own efforts, including, but not limited to, the following:

m. Direct-to-physician and direct-to-pharmacist promotion through sales representatives;

n. Promotion through funding and manipulation of so-called "educators" who organize and arrange continuing medical education (CME) courses for physicians and pharmacists;

o. Formulation of unlawful conspiracies with certain medical marketing and medical "education" entities to promote – without appearing to promote – "off-label" uses;

p. Sponsorship and funding of the production of CME materials;

q. Cultivation and development of so-called "opinion leaders" in local medical communities and support for the careers and research of those physicians, pharmacists, and researchers who advocate off-label uses;

r. Sponsorship of journal supplements and symposia on "off-label" uses;

s. Placing (through sponsorship of limited trials, studies, and surveys) of medical literature databases showing positive effects (already established) on risk factors with the twin purposes of overwhelming any independent study showing negative effects on different risk factors, and causing earnest but time-crunched physicians to be impressed with the sheer quantity of favorable (but redundant) studies on MedLine, or medical library, search;

t. Media advertisements and brochures, some of which were disguised as "educational materials";

u. Coordination of physician-to-physician interactions that are biased toward "off-label" usages;

v. Internet listings that omit important warnings and information; and w. Various other forms of marketing and promotion.

53. Upon information and belief, in accepting the benefits of brand innovator Wyeth's

efforts in promoting "off-label" uses of Cordarone® by sponsoring CME conferences and materials, journal supplements, redundant trials, and the work and careers of favorably disposed opinion leaders, Defendant would sometimes escape disclosure for any role at all in the presentation of its desired view.

54. Additionally, upon information and belief, Upsher-Smith, and/or their agents' pharmaceutical sales representatives and materials and sources actively promoted their generic amiodarone in the stream of commerce for the "off-label" uses openly promoted by Wyeth.

55. At all materials times, despite FDA warnings and thousands of adverse patient experiences, Defendant continued their fraudulent marketing, promotional, and sales practices through the present date.

56. At all material times, which Defendant concealed information about catastrophic injuries and death, and thousands of serious adverse medical events from the FDA, health care professionals, and consumers, including Johnny McDaniel.

57. At all material times, the amiodarone, manufactured and/or supplied by Defendant were and are unaccompanied by proper warnings regarding all possible adverse side effects and comparative severity and duration of such adverse effects; the warnings given did not and do not accurately reflect the severity or duration of the adverse side effects or the true potential and/or likelihood or rate of the side effects. This is particularly so with regard to "off-label" use.

58. At all material times, Defendant failed to warn of material facts regarding the safety and efficacy of amiodarone.

59. For example, although Defendant knew, should have known, and currently knows that the majority of patients consuming amiodarone are older, including those aged 55 and over such as McDaniel, Defendant has failed and refused to conduct testing, studies, surveys, and/or report the results of same regarding amiodarone use in this age group.

60. At all material times, the amiodarone manufactured, distributed, and/or supplied by Defendant was defective due to inadequate post-marketing warning and instruction because, after Defendant knew or should have known of the risk of injury from amiodarone, especially in "off-label" use, Defendant failed to provide adequate and required warnings to physicians, users or consumers of amiodarone, including the Plaintiff McDaniel, and continued to aggressively sell amiodarone, including for "off-label" use.

61. At all material times, while Defendant concealed this adverse event information, they simultaneously engaged in a massive and fraudulent marketing and promotional scheme in which they aggressively and fraudulently promoted amiodarone for uses never authorized by the FDA. In fact, Defendant marketed, promoted, and "pushed" amiodarone, not as a drug of last resort, but as a drug suitable as an initial therapy and to treat non-life-threatening heart conditions.

62. At all material times, Defendant respectively, also promoted amiodarone for heart

conditions less severe than life-threatening ventricular arrhythmia (the only purpose for which the drug originally received FDA approval).

63. Defendant engaged in a conspiracy of silence regarding "off-label" use, choosing to market and promote the drug for "off-label" use, and then feigning ignorance before the FDA, health care providers, and consumers. They failed and refused to conduct thorough testing on the side effects, despite knowing that their scheme to promote the drug for "off-label" uses had been, and continues to be, successful.

64. Defendant has engaged in this calculated and coordinated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the use of amiodarone, and did so because the prospect of significant future profits outweighed their concern regarding health and safety issues, all to the significant detriment of the public and Johnny McDaniel.

65. At all material times, Defendant's affirmative misrepresentations and omissions have so infected the market in the United States that physicians and consumers relied on Defendant's fraud, respectively, to the detriment of their patients and themselves.

66. Nevertheless, at all material times, the warnings for amiodarone, in effect during the relevant time period were vague, incomplete, and/or otherwise wholly inadequate, both substantively and graphically, to alert prescribing physicians,

pharmacists, consumer patients and McDaniel of the actual risks associated with this drug.

67. At all material times, Defendant's deception, concealment, and fraudulent marketing and promotion has been so pervasive throughout the United States, that prescribing physicians and consumer patients have during the relevant time period still believe that amiodarone, is an acceptable initial, secondary, or otherwise early-stage anti-arrhythmic intervention. These deceptive techniques served (and continue to serve) Defendant in several ways, including: (1) instilling Defendant's desired view about the drug's "off-label" uses among health care providers; (2) Defendant hoped that, by concealing its agency in these activities, they would escape the legal ramifications of its unlawful promotional activities; and (3) boost Defendant's profits for the drug.

68. At all material times, Defendant owed a duty to the health care providers, consumer patients, and McDaniel herein, to engage in honest and non-deceptive practices; exercise due care under the circumstances, to exercise due care in the design, manufacture, marketing, promotion, sale, and distribution of amiodarone; to provide a reasonably safe and non-defective drug; to provide adequate and appropriate warnings for said drug; to comply with federal guidelines, rules, and regulations; and/or to sell and distribute the drug in accordance with FDA restrictions.

69. At all material times, Defendant marketed amiodarone, as having approval, characteristics, uses, and benefits that the drug did not have.

70. At all material times, Defendant, did design, create, test, develop, label, sterilize, package, manufacture, market, promote, advertise, distribute, sell, warn, and/or otherwise caused the product to be placed into the stream of commerce, and ultimately to be ingested by McDaniel.

71. At all material times, Defendant willfully failed and refused to actively and affirmatively monitor amiodarone's "off-label," unapproved uses insofar that such uses caused catastrophic injuries and death. Defendant however, continued to sell amiodarone for unapproved uses.

72. At all material times, Defendant engaged in a continuing course of fraud, concealment, material nondisclosure and omission, upon Plaintiffs which prevented Plaintiffs from knowing or having reason to know of Defendant's misconduct.

V. Amiodarone Did Not Undergo The Rigorous FDA Approval Process Required For Federal Preemption

73. Brand manufacturer Wyeth introduced Cordarone® into the United States' stream of commerce. Wyeth received approval for Cordarone® from the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Furthermore, despite repeated requests by the FDA at the outset of the review process and throughout the history of the drug, neither Wyeth, Upshaw the maker of the "other"

brand name version of amiodarone or the generic drug manufacturers of the product have submitted the drug to the rigorous randomized clinical trials required for FDA drug approval.

74. Amiodarone as the drug is commonly known was developed in Belgium in the 1960's as a drug for treating a common heart condition known as angina. At that time, amiodarone was released for marketing in most countries OTHER than the United States.

75. The misunderstanding and use of amiodarone as a drug "with little side effects" became widespread except in the United States. In the 1970's American Doctors began obtaining amiodarone from Canada and Europe for use in their patients with life-threatening arrhythmias who did not respond to other drugs. This activity was sanctioned by the FDA but only on a limited basis. Initial results were promising and by the mid-1980's literally tens of thousands of Americans were taking the drug without FDA approval or testing. American doctors apparently monitored the conditions of their patients more rigorously than their colleagues around the world because they found the drug produced a bizarre series of side effects that doctors around the world seemed to have missed and that were not caught because of the lack of testing or randomized trials.

76. The FDA was essentially forced to release amiodarone for marketing in the United States by the mid-1980's when foreign manufacturers of the drug threatened to cut off the supply to Americans after having supplied the drug for free to thousands of Americans for over five years.

77. As a result, unlike any other drug in modern history, amiodarone became FDA approved without rigorous, FDA sanctioned randomized clinical trials. The legal requirements for preemption applied to drug litigation for FDA approved drugs are not present in amiodarone. Amiodarone has never been subjected to double blind testing as mandated by the FDA.

78. Amiodarone has been determined to affect many different organs in many ways. First, the drug takes many weeks to achieve the maximum effectiveness. Amiodarone is literally "stored" in most of the tissues of the body and to "load" the body with the drug all the tissues need to be saturated. Therefore, the typical loading regimen of amiodarone is to use extremely large dosages of the drug for the first week to two weeks then to taper the dosage over the next month. It is not unusual to give a patient 1200 to 1600 mg dosage a day when starting the drug and to maintain the patient on as little as 100 to 200 mg per day on a chronic basis.

79. Amiodarone leaves the body very slowly. The drug is not excreted like most drugs through the liver or kidney but is only lost when amiodarone containing cells such as skin cells or cells from the GI tract or lost. Therefore, even when it is decided that the patient needs to stop taking amiodarone the drug remains in the system in measurable quantities for months and even years.

80. Most importantly, because the drug is stored in many different types of tissues it can cause side effects that affect many different types of organs. Some of the side effects take months and years to develop. Constant diligence is needed.

81. Amiodarone causes many horrific side effects that have resulted in its restricted use in the United States including; causing blindness, it causes deposits to form on the cornea of the eyes, a condition in virtually everyone who takes the drug; amiodarone causes a very disfiguring blue-grey discoloration of the skin, generally in areas of exposure to the sun; amiodarone often sensitizes the skin to sunlight so that even trivial exposure results in severe sunburns; amiodarone causes hypothyroidism-low thyroidism, - a condition relatively easy to treat with thyroid medication. Some patients develop hyperthyroidism-high thyroid, which is more dangerous and more difficult to treat. Amiodarone can cause liver toxicity; therefore, liver enzymes need to be monitored periodically. Amiodarone can cause severe gastric reflux, caused by a paralysis of the sphincter at the end of the esophagus.

82. The most serious side effect of amiodarone and the one requiring the patient Medication Guide is pulmonary toxicity-lung disease. Amiodarone produces two types of lung disease-first, acute pulmonary syndrome, which looks and acts like typical pneumonia, with a sudden onset of cough and shortness of breath, a condition that rapidly improves once the amiodarone is stopped. The second type is more dangerous. This condition involves a gradual, almost unnoticeable, stiffening of the lungs that both the doctor and patient overlook until finally severe irreversible lung damage is done. This condition can occur quickly after the taking of the drug or can occur years after the drug has begun. Lung toxicity has been found by the FDA to be 17% and fatalities from pulmonary toxicity have been found to be 10% of those taking the drug. These

statistics come from those taking the drug for conditions the drug is not approved for- arterial fibrillation, as well as the ventricular condition it is approved for as a drug of last resort after other treatments have been tried and have failed.

83. Amiodarone did not undergo the rigorous clinical randomized trials all other FDA approved drugs other than a few "grandfathered" drugs with long market histories have undergone. Despite repeated requests, demands and even threats from the FDA the manufacturers of amiodarone and its FDA labeled "brand-names" Wyeth's Cordarone and Upshaw's Pacerone®, have never undergone the type of clinical trials that would show its defects or the benefits verses the risks associated with the drug's use. Despite the economic argument that the patent has expired, or that the costs of testing is too high to justify the investment amiodarone continues to generate enormous revenues for the drug manufacturers without the public having the protection of FDA randomized clinical trials.

84. The only trials amiodarone underwent were non-scientific, reporting of a combination of various patient results combined to obtain statistical data that is neither randomized or reliable and which interestingly enough did not even provide the statistical data that has been determined by the FDA to be accurate for the drug and required in the black box labeling of the product. Obviously, this combination of reporting of various patients was non- scientific and cannot serve as the basis for a claim of preemption.

85. Without rigorous, scientific, clinical trials and randomized testing approved by the FDA the reasons for FDA preemption do not exist and cannot be sustained. Neither the so-called 'brand names" or the generic versions of the drug offer any protection to the public from the FDA approval process. Since the manufacturers will not undergo FDA approved testing they cannot use the FDA approval process as a shield from liability when sued. None of the reasons articulated by the United States Supreme Court for the protection preemption provides are present with amiodarone. None of the costs benefits analysis is present. In addition, none of the regulatory analysis argument and certainly no Federalism argument are present to support preemption.

86. This is not to say the FDA completely disregarded its regulatory or enforcement powers regarding amiodarone. While no testing justifying preemption was ever performed, when the statistical evidence of the dangers of amiodarone and its many side effects became known, the FDA repeatedly amended the labeling requirements for amiodarone, mostly resulting from public pressure and enacted a requirement that the drug manufacturer directly provide the patient a FDA approved "Medication Guide" by ensuring distribution of the Medication Guides to the distributors and then to the patient along with the drug. Due to the failure to conduct required randomized clinical testing by the Wyeth, Plaintiff is not preempted from claiming the Defendant illegally marketed the product for "off-label" use, and is not preempted from claiming that the product itself is unreasonably dangerous as it was packaged, marketed, designed, manufactured

and sold. Most importantly, Plaintiff is not preempted from claiming Defendant failed to warn of the dangers of the product by failing to provide the FDA required "Medication Guide" consisting of ONLY language the FDA approved to go directly to the patient. The failure to provide the FDA "Medication Guide" is a stronger claim than merely alleging the package insert or labeling fails to inform or warn patients or consumers of the dangers of the product. 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.

FIRST CAUSE OF ACTION

(Strict Products Liability – Failure to Warn)[25]

87. Plaintiff incorporates by reference all preceding paragraphs of this Amended Complaint as though set forth in their entirety and further alleges as follows:

88. At all times relevant to this action, Defendant engaged in the business of designing, manufacturing, testing, marketing, labeling, distributing and placing into the stream of commerce

[25] Plaintiff recognizes that the Court has dismissed this Cause of Action as referenced in its Order dated January 26, 2017, attached hereto as Exhibit 1. This Cause of Action remains in tact in this Amended Complaint to preserve the issue for appeal.

amiodarone for sale to, and use by, members of the public including Plaintiff.

89. Amiodarone posed increased risks of harm and side effects that were known or knowable to Defendant by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of amiodarone. Defendant knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein. Defendant consciously disregarded this increased risk of harm by failing to warn or such risks; unlawfully concealing the dangerous problems associates with the "off-label" use of amiodarone; and continuing to market, promote, sell and defend such use of amiodarone without requiring the concurrent dissemination of the Medication Guide.

90. Amiodarone that was manufactured, distributed, and sold by the Defendant to Plaintiff was in a defective condition that was unreasonably and substantially dangerous to any users of ordinary consumers of the device, such as Plaintiff. Such ordinary consumers, including Plaintiff, would not and could not have recognized or discovered the potential risks and side effects of amiodarone as set forth herein.

91. The warnings and directions provided with amiodarone by Defendant failed adequately to warn of the potential risks and side effects of amiodarone and the dangerous propensities of said medication, which risks were known or were reasonably scientifically knowable to Defendant when, among other things, they failed to ensure the Medication Guide was provided to all consumers, including Plaintiff.

92. Defendant's amiodarone products were expected to and did reach Plaintiff and his physicians and pharmacists without substantial change in their condition as manufactured, distributed, and sold by Defendant. Additionally, Plaintiff's physician prescribed and Plaintiff used amiodarone in the manner in which amiodarone was intended to be used by Defendant, making such use reasonably foreseeable to Defendant.

93. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, including death. As a direct and proximate result, Plaintiff expended money for medical bills and expenses. Plaintiff is entitled to compensatory and equitable damages in an amount to be proven at trial.

94. Defendant's lack of sufficient instructions or warnings prior to, on, and after the date of Plaintiff's initial use of amiodarone, including but not limited to failing to ensure he was timely provided the Medication Guide, was a substantial factor in causing Plaintiff's injuries, losses and damages, as described herein.

SECOND CAUSE OF ACTION

(Negligence – Failure to Warn)[26]

95. Plaintiff incorporates by reference all preceding paragraphs of this Amended Complaint as

[26] Plaintiff recognizes that the Court has dismissed this Cause of Action as referenced in its Order dated January 26, 2017, attached hereto as Exhibit 1. This Cause of Action remains in tact in this Amended Complaint to preserve the issue for appeal

though set forth in their entirety and further alleges as follows:

96. At all relevant times, Defendant engaged in the business of designing, manufacturing, testing, marketing, labeling, distributing and placing into the stream of commerce amiodarone for sale to, and use by, members of the public.

97. Amiodarone posed increased risks of harm and side effects that were known or knowable to Defendant by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of amiodarone. Defendant knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein. Defendant negligently disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with the "off-label" use of amiodarone; and continuing to market, promote, sell and defend such use of amiodarone.

98. The warnings and directions provided with amiodarone by Defendant failed adequately to warn of the potential risks and side effects of amiodarone and the dangerous propensities of said medication, which risks were known or reasonably scientifically knowable to Defendant by, among other things, not providing the Medication Guide as required by law. Defendant owed a duty to Plaintiff to ensure Plaintiff and his physicians were adequately and completely warned of all potential serious complications regarding the use of amiodarone and received the Medication Guide. As alleged above, Defendant knew and had reason to

know that amiodarone cause increased risk of harm to the Plaintiff and other consumers like him. Defendant disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with the use of amiodarone; and continuing to market, promote, sell and defend amiodarone.

99. Defendant, as the manufacturers, designers and marketers of the amiodarone medication ingested by Plaintiff, owed a duty of care to Plaintiff and other consumers of amiodarone, to ensure they receive proper warnings regarding the risks of use of amiodarone. Plaintiff and/or his physicians reasonably relied upon Defendant's representations that amiodarone was not only appropriate (FDA approved) for the treatment of atrial fibrillation but also was an appropriate "first line" drug used in the treatment of this condition. Further, Plaintiff reasonably relied upon Defendant to disclose all serious side effects in the use of amiodarone so those side effects may be considered by the physician in his prescribing choices.

100. Amiodarone drugs ingested by Plaintiff were expected to and did reach Plaintiff and his physicians and pharmacist without substantial change in their condition as manufactured, distributed, and sold by Defendant. Additionally, Plaintiff used amiodarone in the manner in which amiodarone was intended to be used by Defendant, making such use reasonably foreseeable to Defendant.

101. As a direct and proximate result of Defendant's manufacture, distribution, and sale of amiodarone, Plaintiff suffered the injuries, losses and damages herein described.

102. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, including death. As a direct and proximate result, Plaintiff expended money for medical bills and expenses. Plaintiff is entitled to compensatory and equitable damages in an amount to be proven at trial.

THIRD CAUSE OF ACTION

(Negligence – Marketing and Sale)[27]

103. Plaintiff incorporates by reference all preceding paragraphs of this Amended Complaint as though set forth in their entirety and further alleges as follows:

104. Prior to, on, and after the date of Plaintiff's decedent's use of amiodarone, Defendant was aware that the FDA had not approved amiodarone for the treatment of atrial fibrillation. To the contrary, because of its dangers, amiodarone was only FDA approved for the treatment of ventricular fibrillation as a drug of last resort after all other treatments had failed. Despite this, Defendant marketed and sold amiodarone for the treatment of atrial fibrillation. Not only was it marketed by Defendant in an "off-label" manner, it was marketed and sold as a "first line" drug to be used in the treatment of atrial fibrillation. Defendant owed a duty to Plaintiff to market and sell

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amiodarone for uses approved by the FDA and for uses for which it has been established as efficacious and safe. As alleged above, Defendant either knew or reasonably has reason to know that amiodarone was not approved for the treatment of atrial fibrillation and was most certainly not an appropriate first line treatment. Defendant disregarded the risk of harm create by the marketing and sale of amiodarone for these "off-label" uses.

105. Defendant, as the manufacturers, designers and marketers of amiodarone, owed a duty of care to Plaintiff and other consumers of amiodarone to ensure it marketed and sold it only for approved uses. Instead, Defendant engaged in a campaign to market the drug for "off-label" uses, in particular for the treatment of atrial fibrillation. This concerted and systemic effort to persuade physicians that amiodarone was not only safe and efficacious for the treatment of atrial fibrillation but also approved for that use, has led a generation of cardiologists and other cardiac specialists to incorrectly believe amiodarone is appropriate for the treatment of atrial fibrillation.

106. Defendant's amiodarone drug products were expected to and did reach Plaintiff's decedent and his physician and pharmacists without substantial change in their condition as manufactured, marketed, and sold by Defendant. Additionally, Plaintiff's decedent's physician prescribed, and Plaintiff used, amiodarone in the manner in which amiodarone was marketed and sold by Defendant, making such use reasonably forseeable to Defendant.

107. As a direct and proximate result of Defendant's manufacture, marketing, and sale of

amiodarone, Plaintiff's decedent suffered the injuries, losses and damages herein described.

108. Defendant's negligent marketing and sale of amiodarone was a substantial factor in causing Plaintiff's decedent's injuries, losses and damages, as described herein.

109. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff's decedent sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, including death. As a direct and proximate result, Plaintiff's decedent expended money for medical bills and expenses. Plaintiff is entitled to compensatory and equitable damages in an amount to be proven at trial.

FOURTH CAUSE OF ACTION

(Negligence *Per Se*)[28]

110. Plaintiff incorporates by reference all other paragraphs of this Amended Complaint as if fully set forth herein.

111. Defendant owed a duty to Plaintiff's decedent to market and sale amiodarone only for uses approved by the FDA and for uses for which it has been established as efficacious and safe.

112. Defendant violated this duty by marketing, promoting and selling amiodarone for

[28] Plaintiff recognizes that the Court has dismissed this Cause of Action as referenced in its Order dated January 26, 2017, attached hereto as Exhibit 1. This Cause of Action remains in tact in this First Amended Complaint to preserve the issue for appeal.

uses not approved by the FDA. Defendant violated this duty by selling amiodarone without supplying the Medication Guide required by the FDA. This concerted and systemic effort to persuade physicians that amiodarone was not only safe and efficacious for the treatment of atrial fibrillation but also approved for that use, has led a generation of cardiologists and other cardiac specialists to incorrectly believe amiodarone is appropriate for the treatment of atrial fibrillation.

113. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff's decedent sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, including death. As a direct and proximate result, Plaintiff's decedent expended money for medical bills and expenses. Plaintiff is entitled to compensatory and equitable damages in an amount to be proven at trial.

FIFTH CAUSE OF ACTION

(Fraud and Deceit)

114. Plaintiff incorporates by reference all other paragraphs of this Amended Complaint as if fully set forth herein.

115. Defendant, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell amiodarone, owed a duty to provide accurate and complete information to Plaintiff's decedent, his pharmacist and physician, and the public regarding amiodarone, including and more particularly, specific information and facts such as included in the Medication Guide

concerning the dangers and risks to Plaintiff's decedent's health which Plaintiff's decedent would have been aware if Defendant had complied with the requirements associated with the mandatory distribution of the Medication Guide directly to Plaintiff's decedent. Important facts that did not reach McDaniel such as, amiodarone is only for situations of last resort and only in situations involving ventricular tachycardia, not atrial fibrillation from which McDaniel suffered. Important facts that would have saved McDaniel's life.

116. Defendant misled Plaintiff's decedent, Plaintiff's decedent's pharmacist and physician, and the public into believing that amiodarone was safe and effective for use in the treatment of atrial fibrillation, and engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals and patients to use amidarone by offering and promoting amiodarone for sell via its websites and distribution centers as set forth above, even though Defendant knew or should have known that amiodarone was unreasonably unsafe for the specific illness suffered by Plaintiff's decedent and thousands of other individuals affected by atrial fibrillation. Defendant also failed to take steps to affirmatively warn health care professionals and the public to include Plaintiff's decedent about the life threatening pulmonary fibrosis and other risks of amiodarone designed, marketed and sold by Defendant.

117. Defendant's advertising program and promotional items to include offering the dangerous drug for sell via its website and distribution centers, by containing affirmative misrepresentations and

omitting material facts such as the risks of death from pulmonary fibrosis and other serious and dangerous side effects, falsely and deceptively sought to create the image and impression that amiodarone was safe for human use for the treatment of atrial fibrillation, had no unacceptable side effects or more specifically failed to provide information to Plaintiff's decedent via the mandated Medication Guide which outlined the inherent dangers for atrial fibrillation patients such as Plaintiff's decedent, and did not inform Plaintiff's decedent that this dangerous drug would result in a painful death.

118. Defendant actively concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of amiodarone in a manner that any reasonable person, to include Plaintiff's decedent, would view the omission as material to any decision to take the medication. Defendant, through their promotional practices, deceived potential treating physicians, Plaintiff, other patients, and the public. Defendant falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiff, regarding the safety of amiodarone in terms of its "off-label" use. More specifically, Defendant omitted and failed to provide the specific warnings of serious life threatening side effects such as pulmonary fibrosis, outlined in the Medication Guide, because the Medication Guides were not distributed in such a manner by the Defendant to insure that the Medication Guide and its warnings were provided to McDaniel each time McDaniel picked up his prescription from his pharmacist at the Naval Branch Health Clinic, Millington, Tennessee beginning in

May, 2015. Omission of the specific warnings and details that could have saved Plaintiff's decedent's life included the fact that amiodarone could "cause serious side effects that can lead to death including: lung problems; liver problems; worsening heartbeat problems; and thyroid problems"[29] and that amiodarone "should only be used in people with life-threatening heartbeat problems called ventricular arrhythmias, for which other treatments did not work or were not tolerated**."**[30] The Medication Guide specifically notes in pertinent part that amiodarone is a drug of last resort and only to be used in situations involving ventricular tachycardia. Defendant and its agents failed to provide this critical and life saving information to McDaniel and failed to put in place a process that would protect McDaniel by insuring he received the life saving information and did not rely on false or misleading information or the omission of important safety information by Defendant. The failure by Defendant and its agents to provide the critical information and content of the Medication Guide, or provide some process or procedure that insured distribution of the omitted information to the Plaintiff's decedent, fraudulently misrepresented the safety of the drug for patients such as McDaniel and induced McDaniel to take the drug, enriching the Defendant while causing the death of McDaniel.

119. By failing to distribute key warnings of the Medication Guide in a manner that would insure direct distribution to the Plaintiff's decedent, Defendant expressly denied that amiodarone created an increased risk of injury and took affirmative steps

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[29] Amiodarone Medication Guide

[30] Id.

to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from amiodarone in terms of its "off-label" use. By failing to provide Mediation Guides sufficient to insure that Plaintiff's decedent would receive the important information and warnings clearly stated in the Medication Guide as related to his physical condition and health the Defendant kept information from the Plaintiff's decedent that was key to his health and safety and in fact caused his untimely and painful death.

120. Defendant did not accurately report the results of adverse events by withholding from the FDA, physicians, Plaintiff, and the public, the truth regarding amiodarone failures for years, all the while undertaking a major advertising campaign to sell amiodarone. Defendant received reports of amiodarone's side effects attributable to "off-label" use from various sources, and withheld this information and maintained it in their possession, while continuing to sell amiodarone to individuals such as Plaintiff's decedent.

121. Defendant effectively deceived and misled the scientific and medical communities regarding the risks and benefits of amiodarone. Defendant failed to fully inform physicians, patients, including Plaintiff's decedent, and the public of the true defects in amiodarone when used for "off label" purposes as with the Plaintiff's decedent, which were known to Defendant, and continued to assure physicians and patients that amiodarone was adequate and reliable for the purpose intended by the continuous offering for sell of this dangerous product through its website and distribution centers.

122. Through the materials they disseminated via Defendants product website and distribution centers, Defendant falsely and deceptively misrepresented or omitted a number of material facts regarding amiodarone as set forth in detail above and as particularly outlined in the Medication Guide.

123. Defendant possessed evidence and knowledge that amiodarone caused serious and life threatening adverse side effects such as those suffered by Plaintiff's decedent. Nevertheless, Defendant continued to market amiodarone to atrial fibrillation patients such as Plaintiff's decednt by providing false and misleading information with regard to its safety to Plaintiff's decedent and Plaintiff's decedent's treating physician and by not provided the information contained in the mandated Medication Guide..

124. Among Defendant's numerous misrepresentations and misleading omissions to Plaintiff's decedent, Plaintiff's decedent's physician and pharmacist and the general public are Defendant's assurances that amiodarone was a safe and effective drug for the treatment of atrial fibrillation. Defendant made such statements even after they became aware of numerous and serious complications with amiodarone. Defendant did not reveal (and instead actively concealed) their knowledge of numerous and serious complications with amiodarone. Despite their knowledge of serious problems with amiodarone, Defendant continued and continue to market amiodarone to atrial fibrillation patients such as Plaintiff's decedent and does so without insuring that the important warnings outlined in the Medication Guide are provided as mandated.

125. Defendant also concealed from Plaintiff's decedent and Plaintiff's decedent's pharmacist and physician the material facts they were obligated to disclose, including that amiodarone was not FDA approved for the treatment of atrial fibrillation, was not an appropriate "first line of treatment" for atrial fibrillation, is required to be accompanied by a Medication Guide intended to warn the consumer of the serious, life-threatening complications from the use of amiodarone and was approved by the FDA for a very limited use without any associated clinical trials establishing the safety and efficacy of the drug.

126. Defendant engaged in all the acts and omissions described above with the intent that Plaintiff's decedent and his physician and pharmacist reasonably would rely on the misrepresentation, deception and concealment of material facts such as those outlined in the Medication guide in deciding to use amiodarone rather than another product for the control of atrial fibrillation.

127. Plaintiff's decedent and/or Plaintiff's decedent's pharmacist, and physician justifiably relied to their detriment on Defendant's misrepresentations as set out above. The reliance proximately caused the injuries and damages described in this Amended Complaint.

128. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff's decedent sustained severe physical injuries, economic losses and other damages, including death. As a direct result, Plaintiff expended money for medical bills and expenses. Plaintiff is entitled to compensatory and exemplary damages in an amount to be proven at trial.

SIXTH CAUSE OF ACTION

WRONGFUL DEATH

129. Plaintiff incorporates by reference all other paragraphs of this Amended Complaint as if fully set forth herein.

130. The death of Johnny McDaniel was directly and proximately caused by the negligent actions of Upsher-Smith in the off-label and other negligent promotional and marketing activities associated with the sale of amiodarone and the negligent actions of Defendant Upsher-Smith for their failure to warn by providing up to date and required labeling and to provide Medication Guides to distributors for the ultimate distribution of the Medication Guides to patients as required by FDA rules and regulations and as generally related to the manufacture, marketing, distribution and sale of Cordarone®/amiodarone as described herein.

WHEREFORE, Plaintiff, demands judgment against the Defendant for compensatory damages, together with applicable interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

VIII. Demand For Jury Trial

Plaintiff in the above-styled case hereby demands a trial by jury of all issues so triable as a matter of right.

This the 6th day of February, 2017

Respectfully Submitted,

By: */s/ E. Kirk Wood*
Attorney for Plaintiff

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CERTIFICATE OF SERVICE

This is to certify that on the 6th day of February, 2017, a copy of the foregoing was served on the following parties to this proceeding via Electronic Filing and/or U.S. Mail, properly addressed and first class postage pre-paid:

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/s/ *E. Kirk Wood*
E. Kirk Wood, Attorney for the Plaintiff

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

RITA McDANIEL, Individually and as Personal Representative of the Estate of JOHNNY F. McDANIEL, Deceased,	)	
Plaintiff,	)	No. 2:16-cv-02604-JPM-cgc
v.	)	
UPSHER-SMITH PHARMACEUTICALS, INC.,	)	
Defendant.	)	

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION TO DISMISS

Before the Court is Defendant Upsher-Smith Pharmaceuticals, Inc.'s Motion to Dismiss, filed August 22, 2016. (ECF No. 17.) For the reasons stated below, the Motion to Dismiss is GRANTED in part and DENIED in part.

I. BACKGROUND

A. Factual Background

Rita McDaniel brings an action on behalf of the estate of Johnny F. McDaniel for wrongful death. Plaintiff asserts that her husband was prescribed 200 mg amiodarone tablets in May 2015 for treatment of his non-life-threatening atrial fibrillation. (Compl. at 11, ECF No. 1.) The amiodarone tablets were manufactured and sold by Upsher-Smith Pharmaceuticals, Inc as a generic version of Wyeth's Cordarone under the name Paecerone. (Id. at 12; Def.'s Mem. for Mot. to Dismiss at 1-2, ECF No. 17-1.) Wyeth has received approval from the Food and Drug Administration (FDA) to market and sell amiodarone as a drug of last resort for patients suffering from life-threatening ventricular fibrillation and ventricular tachycardia. (Compl. at 4, ECF No. 1; Def.'s Mem. for Mot. to Dismiss at 2, ECF No. 17-1.) Plaintiff asserts that Defendant promoted the "off-label" use of amiodarine as an initial treatment for patients with atrial fibrillation, though Defendant was aware that such a use had not received FDA approval and may result in serious pulmonary illness, toxicity, and death. (Id. at 4-5.) Plaintiff asserts that her husband was given the amiodarone for off-label use, though he was not in a situation of "last resort" as to the management of his atrial fibrillation and his condition was not life threatening. (Id. at 5, 11.) Mr. McDaniel received his medication at the Naval Branch Health Clinic. (Id.) Plaintiff further asserts that Mr. McDaniel did not receive the FDA Medication Guide and current warning labels for the prescriptions. (Id. at 11.) Plaintiff alleges

that Mr. McDaniel developed several pulmonary complications as a result of the inappropriate off-label use. (Id. at 15.) Mr. McDaniel was admitted to Methodist LeBonheur Hospital on June 22, 2015 and died on July 22, 2016 at the age of 78. (Id. at 5, 15.) Plaintiff asserts six claims: (1) strict liability/failure to warn, (2) negligence – failure to warn, (3) negligence – marketing and sales, (4) negligence per se, (5) fraud and deceit, and (6) wrongful death. (Id. at 26-36.) Plaintiff alternatively requests that she be allowed to file an amended complaint. (Pl.'s Resp. at 17-20, ECF No. 23.)

B. Procedural Background

Plaintiff filed a Complaint on July 21, 2016. (ECF No. 1.) Defendant filed a Motion to Dismiss on August 22, 2016. (ECF No. 17.) On September 9, 2016, the Court entered an order staying all deadlines in the case and continuing the Rule 16 scheduling conference pending the Court's ruling on the instant Motion to Dismiss. (ECF No. 22.) Plaintiff filed a response on September 21, 2016. (ECF No. 23.) Defendant filed a reply on October 5, 2016. (ECF No. 24.)

II. Legal Standards

A. Motion to Dismiss

A court may dismiss a claim for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S.

662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

> A complaint must contain a short and plain statement of the claim showing that the pleader is entitled to relief. . . . A claim is facially plausible when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. . . . [T]he court need not accept as true allegations that are conclusory or require unwarranted inferences based on the alleged facts.

Newberry v. Silverman, 789 F.3d 636, 640 (6th Cir. 2015) (citations and internal quotation marks omitted). "Plausibility is not the same as probability, but it requires 'more than a sheer possibility that a defendant has acted unlawfully.'" Mik v. Fed. Home Loan Mortg. Corp., 743 F.3d 149, 157 (6th Cir. 2014) (quoting Iqbal, 556 U.S. at 678). A court must "construe[] the complaint in a light most favorable to the plaintiff." HDC, LLC v. City of Ann Arbor, 675 F.3d 608, 611 (6th Cir. 2012).

In alleging fraud, Federal Rule of Civil Procedure 9(b) requires a plaintiff to plead with particularity "the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." Fed. R. Civ. P. 9(b); Sanderson v. HCA-The Healthcare Co., 447 F.3d 873, 877 (6th Cir. 2006) (quoting Yuhasz, 341 F.3d 559, 563 (6th Cir. 2003)); Glassner v. R.J. Reynolds Tobacco Co., 223 F.3d 343,

346 (6th Cir. 2000) ("[A] complaint alleging fraud must allege with particularity those circumstances constituting fraud"). At a minimum, a plaintiff must "allege the time, place and contents of the misrepresentation(s) upon which he relied." Bender v. Southland Corp., 749 F.2d 1205 (6th Cir. 1984).

B. Federal Preemption

The Supremacy Clause establishes the concept of federal preemption, stating that federal law "shall be the supreme Law of the Land." U.S. Const., Art. VI, cl. 2. State law is preempted by federal law if: 1) Congress expressly states its intention to preempt state law; 2) Congress intends for federal law to "occupy the field"; or 3) it is impossible to comply with both state and federal requirements, or compliance with state law would create an obstacle to the achievement of Congress's purposes. Crosby v. National Foreign Trade Council, 530 U.S. 363, 373-74 (2000).

In Buckman, the Supreme Court found that the plaintiffs' state law claims were preempted where the claims arose solely from the alleged violation of FDCA requirements, rather than parallel state-law causes of action. Buckman Co. v. Plaintiff's Legal Committee, 531 U.S. 341 (2001). The Supreme Court stated that "certain state-law causes of actions that parallel federal safety requirements" may be allowed; however, it is incorrect that "any violation of the FDCA will support a state-law claim." Id. at 352. The Court emphasized that the plaintiffs were not "relying on traditional state tort law which had predated the federal enactments in question[]" but that "the

existence of these federal enactments is a critical element in their case." Id. at 353. In In re Darvocet, the Sixth Circuit found that a plaintiff's claims for statutory negligence were preempted by Buckman as they were premised on the defendants' violation of the FDCA. In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation, 756 F.3d 917 (6th Cir. 2014). The Sixth Circuit reiterated that "the FDA has the exclusive power to enforce the FDCA" and "there is no private right to enforce the statute." Id. at 936. If a claim would not exist in the absence of the FDCA, it is impliedly preempted. Loreto v. Proctor & Gamble Co., 515 Fed.Appx. 576, 579 (6th Cir. 2013) ("This theory of liability depends entirely upon an FDCA violation . . . the theory is impliedly preempted by federal law.").

1. Failure to Warn

The requirement to provide a medication guide is found in the Food, Drug and Cosmetic Act (FDCA), 21 C.F.R. § 208.24. (Compl. at 12-14, ECF No. 1.) 21 C.F.R. § 208.24 requires that "[e]ach manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients . . ." 21 C.F.R. § 208.24(b). Additionally, the FDA requires that "Medication Guides be issued with certain prescribed drugs . . . when the Agency determines that: certain information is necessary to prevent serious adverse effects, patient decision-making should be informed by information about a known serious side effect with a product, or patient adherence to directions for the use of a product

are essential to its effectiveness." Medication Guides, U.S. Food & Drug Administration, http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm (including Cordarone and Pacerone on the list of products for which Medication Guides are available).[1]

2. "Off-Label" Promotion

The concept of "off-label use and promotion" is derived from and defined by the FDCA regulatory system and has no state- law equivalent. Hafer v. Medtronic, Inc., 99 F.Supp.3d 844, 857 (W.D. Tenn. 2015). Off-label use "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." Id. at 858 (quoting Buckman, 531 U.S. at

[1] The parties cite cases from other circuits with similar facts. Defendant cites Perdue, a case in which the Eastern District of North Carolina found that, since the requirement to provide a medication guide is based solely in the requirements of the FDCA and related regulations and not under the state common law, the plaintiff's claims based upon failure to provide such a guide were preempted under Buckman. Perdue v. Wyeth Pharmaceuticals, Inc., 2016 WL 3951091, at *5 (E.D.N.C. July 20, 2016). In contrast, Plaintiff cites Eckhardt v. Qualitest Pharmaceuticals, Inc., a case in which the Fifth Circuit stated that a claim against a generic drug manufacturer for failure to provide FDA-approved warnings would be a violation of both state and federal law and therefore would not be preempted. Eckhardt v. Qualitest Pharms., Inc., 751 F.3d 674 (5th Cir. 2014) (affirming the district court's dismissal of the plaintiff's claim nevertheless, as the plaintiff failed to adequately allege the failure to warn claim); see also Rusk v. Wyeth-Ayerst Laboratories, Inc., 2015 WL 3651434 (W.D. Tex. June 11, 2015) (applying Eckhardt to hold that a claim for failure to provide a medication guide was not preempted). The Court considers the reasoning in such cases only persuasive and not binding authority.

350). The FDCA does not provide a private cause of action; therefore, any claim based solely on off-label promotion is impliedly preempted. See Hafer, 99 F.Supp.3d at 856-57; Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804 (1986) (holding that the FDCA does not provide a private cause of action). Even if the claim is formally asserted under state law, the claim may still be preempted if it is "in substance" a claim for violating the FDCA. Hafer, 99 F. Supp. 3d at 857.

3. Fraud and Deceit

In Hafer, the Western District of Tennessee found that the plaintiff's claim for fraudulent concealment, misrepresentation, and fraud during the promoting and marketing of the product was not preempted. Hafer, 99 F.Supp.3d at 859. The court reasoned that the plaintiff's claim of misrepresentations during promoting and marketing did not provide requirements "different from, or in addition to" federal requirements and so avoided express preemption. Id. The court also noted that Plaintiff's claim was "independently supported by traditional state laws against false and misleading advertising, thereby avoiding implied preemption." Id. "[S]tate fraud-based claims 'are parallel or genuinely equivalent to federal law.'" Id. (quoting Schouest v. Medtronic, Inc., 13 F.Supp.3d 692, 704 (S.D. Tex. 2014)). Similarly, in Loreto, the Sixth Circuit found that a claim of false or misleading statements in marketing of the product was not preempted as the theory "relie[d] solely on traditional state tort law predating the FDCA, and would exist in the absence of the Act." Loreto v. Proctor & Gamble Co., 515 Fed.Appx. 576 (6th Cir. 2013).

C. Motions for Leave to Amend

"Federal Rule of Civil Procedure 15(a)(2) provides that leave to amend shall be freely given when justice so requires." Riverview Health Inst. LLC v. Med. Mut. of Ohio, 601 F.3d 505, 520 (6th Cir. 2010). Rule 15 "plainly embodies a liberal amendment policy," Morse v. McWhorter, 290 F.3d 795, 800 (6th Cir. 2002), that "reinforces the principle that cases should be tried on their merits rather than the technicalities of pleadings," Inge v. Rock Fin. Corp., 388 F.3d 930, 937 (6th Cir. 2004) (quoting Moore v. City of Paducah, 790 F.2d 557, 559 (6th Cir. 1986)) (alterations and internal quotation marks omitted).

A motion for leave to amend a complaint "may be denied where there is undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." Riverview, 601 F.3d at 520 (quoting Foman v. Davis, 371 U.S. 178, 182 (1962)) (internal quotation marks omitted). A proposed amendment is futile "if the court concludes that the pleading as amended could not withstand a motion to dismiss." Midkiff v. Adams Cnty. Reg'l Water Dist., 409 F.3d 758, 767 (6th Cir. 2005) (quoting Martin v. Associated Truck Lines, Inc., 801 F.2d 246, 249 (6th Cir. 1986)).

III. Analysis

Defendant argues that the Complaint must be dismissed on grounds of federal preemption. (Mot. to

Dismiss, ECF No. 17.) Defendant also asserts that Plaintiff's claim of fraud and deceit fails to satisfy the pleading standards of Federal Rule of Civil Procedure 9(b). (Mem. for Mot. to Dismiss at 17, ECF No. 17-1.)

A. Failure to Warn

Plaintiff makes claims of strict products liability – failure to warn (Count 1) and negligence – failure to warn (Count 2), stating that Defendant failed to provide "sufficient instructions or warnings" of the "potential risks and side effects of amiodarone," "including but not limited to failing to ensure [Plaintiff] was timely provided the Medication Guide." (Compl. at 27-28, ECF No. 1.) In his Response to the Motion to Dismiss, Plaintiff clarified that he "does not allege that the contents of the labeling should have been changed," rather, he "alleges that the Medication Guide and its warnings were not provided to him in accordance with the FDA mandate." (Pl.'s Resp. at 12, ECF No. 23.)

The requirement to provide a medication guide is found in the FDCA. Plaintiff has not cited parallel state-law safety requirements to provide a medication guide under Tennessee law. Plaintiff's claims are premised upon Defendant's violation of federal standards for the distribution of medication guides set forth in the FDCA and would not exist "in the absence of the FDCA." Buckman, 531 U.S. at 353. Therefore, Plaintiff's claims based upon failure to warn due to failure to provide a medication guide are preempted under Buckman. The Court grants Defendant's motion to dismiss on Plaintiff's failure-to-warn claims (Counts 1 and 2).

B. "Off-Label" Promotion

Plaintiff claims that Defendant marketed and sold amiodarone in an "off-label" manner as a "first line" drug to be used in the treatment of atrial fibrillation, rather than for uses approved by the FDA, thus asserting that Defendant is liable under the theories of negligence and negligence per se (Counts 3 and 4). (Compl. at 30-32, ECF No. 1.)

Plaintiff's claims are impliedly preempted by the FDCA as both claims are based upon off-label use and promotion, which is a concept that is entirely derived from and defined by the FDCA in substance. See Hafer, 99 F.Supp.3d at 857. As the concept of "off-label" is entirely federal, Plaintiff's claims would not exist in the absence of the FDCA and are therefore impliedly preempted under Buckman. The Court therefore grants Defendant's Motion to Dismiss with regard to Counts 3 and 4.

C. Fraud and Deceit

Plaintiff alleges that Defendant misled him, his physician, scientific and medical communities, the FDA, and the public regarding the safety risks of amiodarane (Count 5). (Compl. at 32-35, ECF No. 1.) Plaintiff alternatively requests that she be allowed to file an amended complaint. (Pl.'s Resp. at 17-20, ECF No. 23.)Defendant argues that "Plaintiff has failed to plead her fraud-based claims with the particularity required under Rule 9(b)" and states that the Court should deny Plaintiff's request for leave to amend the Complaint as any amendment would be futile. (Def.'s Reply at 7-9, ECF No. 24.)

Plaintiff's claim of fraud and deceit is not expressly or impliedly preempted. State claims of fraud and deceit do not provide requirements in conflict with federal requirements. State laws traditionally prohibit fraud and deceit in advertising and marketing as well. Plaintiff, however, fails to allege fraud with the particularity required by Federal Rule of Civil Procedure 9(b). Plaintiff has not included facts regarding the alleged affirmative misrepresentations made during the marketing of the product on which Plaintiff, doctors, or members of the public relied.

Rule 15 contains a liberal amendment policy. Defendant asserts that any amendment to the Complaint would be futile. The Court, however, finds that Defendant would not be unduly prejudiced by virtue of allowing amendment. The Court also finds that amendment of Count 5 would not be futile as it would be possible for Plaintiff to allege additional facts that plead her fraud claim with particularity and the fraud claim would not be preempted by federal law. The Court therefore denies Defendant's Motion to Dismiss with regard to Count 5 and grants Plaintiff leave to file an amended complaint to allege fraud and deceit with particularity.

D. Wrongful Death

Plaintiff brings a claim against Defendant for wrongful death, alleging that the death of Johnny McDaniel was caused by Defendant's negligence (Count 6). (Compl. at 35-36, ECF No. 1.)

Defendant has not addressed the wrongful death claim in its Motion to Dismiss. The wrongful

death claim contains sufficient factual matter to meet the plausibility requirements of Rule 12(b)(6). Defendant's Motion to Dismiss is denied with regards to Count 6 of the Complaint.

IV. CONCLUSION

For the reasons stated above, Defendant's Motion to Dismiss (ECF No. 17) is GRANTED in part and DENIED in part. Counts 1 through 4 of the Complaint are dismissed with prejudice. The Court denies Defendant's Motion to Dismiss Count 6. Plaintiff may file an amended complaint regarding Count 5 within ten (10) calendar days of the entry of this Order.

IT IS SO ORDERED, this 26th day of January, 2017.

/s/ Jon P. McCalla
JON P. McCALLA
UNITED STATES DISTRICT JUDGE

U.S. CONST. art. VI

All debts contracted and engagements entered into, before the adoption of this Constitution, shall be as valid against the United States under this Constitution, as under the Confederation.

This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

The Senators and Representatives before mentioned, and the members of the several state legislatures, and all executive and judicial officers, both of the United States and of the several states, shall be bound by oath or affirmation, to support this Constitution; but no religious test shall ever be required as a qualification to any office or public trust under the United States.

21 U.S.C. § 337

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

* * *

21 C.F.R. § 208.24 Distributing and dispensing a Medication Guide.

(a) The manufacturer of a drug product for which a Medication Guide is required under this part shall obtain FDA approval of the Medication Guide before the Medication Guide may be distributed.

(b) Each manufacturer who ships a container of drug product for which a Medication Guide is required under this part is responsible for ensuring that Medication Guides are available for distribution to patients by either:

(1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or

(2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product.

* * *

[ENTERED: August 3, 2018]

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

1100 East Main Street, Suite 501,
Richmond, Virginia 23219
www.ca4.uscourts.gov

August 3, 2018

TENTATIVE CALENDAR ORDER

No. 17-2263, Latham Bean v. Upsher-Smith Pharmaceauticals, 4:16-cv-01696-RBH

This case has been tentatively calendared for oral argument as follows:

Argument Session: 10/30/18 - 11/1/18

Additional Copies of Briefs & Appendices Due: 08/08/2018

Motions and Notice of Conflicts Due: 08/13/2018

The court requires a total of four paper copies of briefs and appendices in cases that are tentatively calendared for oral argument. If you previously filed one copy of your brief or appendix, you must now file three additional copies. If you have not yet filed your brief, you must file four paper copies and an electronic copy.

The requirement of four paper copies applies to all briefs and appendices, including: Amicus Briefs, Intervenor Briefs, Sealed Versions of Briefs, Public Versions of Briefs, Joint Appendices, Supplemental Appendices, Sealed Volumes of Joint and Supplemental Appendices,

and Paper Copies of the Administrative Record adopted by Petitioner or Appellant as an Appendix.

All paper copies must be **identical** as to cover, binding, page numbering, and other formatting, and must match the electronic copy. No ECF entry is made by counsel when filing additional copies of paper briefs and appendices.

Any motions that would affect the scheduling of argument, including motions to continue, submit on the briefs, or voluntarily dismiss, must be filed by the due date shown above and must state whether opposing counsel consents to the requested relief.

Any scheduling conflict with dates during the argument session must be filed by the due date shown above, using the entry Notice re: conflict with proposed argument dates (form available at http://www.ca4.uscourts.gov/court-forms-fees). Do not file the form if you have no conflicts.

You will be notified either that your case has been scheduled for a date certain during the session or continued to the next available session. After a case has been scheduled for argument, any motion that would affect the argument date must show good cause for the requested relief and that the relief could not have been requested within the period set for notice of conflicts.

The identity of the panel hearing a case is not disclosed until the morning of argument.

For questions regarding scheduling of argument, please call 804-916-2714. For questions regarding required copies, please call 804-916-2700.

/s/ PATRICIA S. CONNOR, CLERK
By: Joseph L. Coleman, Jr., Calendar Clerk

[ENTERED: October 16, 2018]

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT
OFFICE OF THE CLERK

1100 East Main Street, Suite 501
Richmond, Virginia 23219-3517
www.ca4.uscourts.gov

Patricia S. Connor
Clerk

Telephone
804-916-2700

October 16, 2018

TENTATIVELY CALENDARED CASE
CONTINUED

No. 17-2263, Latham Bean v. Upsher-Smith Pharmaceauticals, 4:16-cv-01696-RBH

TO: Counsel

You were previously notified of the tentative assignment of this case to an oral argument session. For scheduling reasons, your case has been continued. You will receive further notice from the court as soon as your case is assigned to another argument session.

Joseph L. Coleman, Jr.
Calendar Clerk
804-916-2714