No. 19-1246

In the Supreme Court of the United States

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

Petitioner,

v.

UPSHER-SMITH LABORATORIES, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF IN OPPOSITION

Mark C. Hegarty
Douglas B. Maddock, Jr.
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, Missouri 64108

Cary Silverman
Counsel of Record
SHOOK, HARDY & BACON L.L.P.
1800 K Street, NW
Suite 1000
Washington, DC 20006
(202) 783-8400
csilverman@shb.com

Counsel for Respondent

QUESTION PRESENTED

Whether a claim that seeks to enforce the federal regulation requiring prescription drug manufacturers to ensure the availability of medication guides for authorized dispensers to distribute to patients is impliedly preempted when the regulation is enforceable only by the federal government and there is no parallel duty to distribute a medication guide under Tennessee law.

CORPORATE DISCLOSURE STATEMENT

Upsher-Smith Laboratories, LLC's sole member is Sawai America, LLC, which is owned by Sawai America Holdings, Inc. and Sumitomo Corporation of Americas. Sawai America Holdings, Inc. is wholly-owned by Sawai Pharmaceuticals Co., Ltd. (Japan). Sumitomo Corporation of Americas is wholly-owned by Sumitomo Corporation (Japan).

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The opinion of the court of appeals (Pet. App. 1a-20a) is reported at 893 F.3d 941. The order of the court of appeals denying rehearing en banc (Pet. App. 33a-34a) is unreported. The district court's order granting respondent's motion to dismiss the amended complaint (Pet. App. 22a-30a) is unreported. The district court's order granting in part and denying in part respondent's motion to dismiss the original complaint (Pet. App. 83a-95a) is reported at 229 F. Supp. 3d 707.

JURISDICTION

The judgment of the court of appeals was entered on June 29, 2018. A petition for rehearing en banc was denied on August 2, 2018. The petition for a writ of certiorari was filed on October 31, 2018. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS

The case involves U.S. CONST. art. VI, 21 U.S.C. § 337(a), and 21 C.F.R. § 208.24(a), (b), (c), and (e).

INTRODUCTION

Petitioner's complaint alleges that respondent violated the federal regulation requiring manufacturers of certain drugs to distribute a medication guide for authorized dispensers to provide to patients with their prescription. In briefing before the district court, petitioner confirmed that her claims are premised on the alleged failure to comply with this federal regulation. Federal law prohibits private enforcement of this regulation and there is no

equivalent requirement to distribute medication guides for patients under Tennessee law. The Sixth Circuit rejected an attempt by petitioner to recast her claims on appeal and affirmed the dismissal on preemption grounds, correctly finding that petitioner was seeking to enforce this federal regulation under the guise of state-law claims. Although the panel was divided on the preemption question, it was a case-specific disagreement based on the specific language in petitioner's allegations and her characterization of those allegations in the district court, and therefore it does not merit this Court's review.

There also is no circuit split on the question here. The Sixth Circuit is the *only* circuit to address whether state-law claims alleging violations of the federal medication guide regulation are preempted. Although petitioner's counsel appealed the same issue in substantially similar cases in the Eleventh and Fourth Circuits, those courts never reached the preemption issue and affirmed the dismissals on state-law grounds. And while petitioner cites several circuit court decisions she describes as in conflict, those decisions are not contrary to the Sixth Circuit's decision.

The petition for a writ of certiorari should be denied.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

The prescription drug at issue is a generic version of amiodarone, an FDA-approved anti-arrhythmic prescription medication. Pet. App. 3a. Prescription drugs like amiodarone are governed by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.

§ 301 *et seq*. A manufacturer seeking U.S. Food and Drug Administration ("FDA") approval to market a new drug must prove that it is safe and effective and that the proposed labeling is accurate and adequate. 21 U.S.C. § 355(b)(1), (d). In 1984, Congress passed the Hatch-Waxman Act, which outlines the process by which generic drugs can obtain FDA approval. *Id.* § 355(j)(2). This allows manufacturers to make generic drugs available "inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011).

Obtaining approval for a generic drug requires showing that the generic drug is "bioequivalent" to the brand-name drug and has the same active ingredients, route of administration, dosage form, and strength. 21 U.S.C. § 355(j)(2)(A). The generic manufacturer must also "show that the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug." *Mensing*, 564 U.S. at 612-13 (citing 21 U.S.C. § 355(j)(2)(A)(v)); *id.* at 613 (generic manufacturer "is responsible for ensuring that its warning label is the same as the brand name's") (citing 21 U.S.C. §§ 355(j)(2)(A)(v); 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7)). This "federal duty of 'sameness'" for generic drug labeling is "ongoing." *Mensing*, 564 U.S. at 613.

FDA regulates and approves all labeling for prescription drugs. 21 C.F.R. § 314.105(c). FDA requires manufacturers to provide health care providers with prescribing information that contains "a summary of the essential scientific information needed for the safe and effective use of the drug."

21 C.F.R. § 201.56(a)(1); *see id.* § 201.57. Required labeling information includes indications and usage, dosage and administration, contraindications, warnings and precautions, adverse reactions, drug interactions, and clinical pharmacology, among many other topics. 21 C.F.R. § 201.57. FDA approves the "exact wording" of the labeling. *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 (2d Cir. 2016) (citations omitted). Prescription drug labeling "is written for the health care practitioner audience, because prescription drugs require 'professional supervision of a practitioner licensed by law to administer such drug[.]'" Final Rule, *Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products*, 71 Fed. Reg. 3922, 3922 (Jan. 24, 2006) (quoting 21 U.S.C. § 353(b)).

In 1998, FDA published new regulations that created additional disclosure requirements for certain prescription drugs that FDA determines warrant distribution of FDA-approved patient information. 21 C.F.R. Part 208. For these products, FDA requires manufacturers to provide distributors, packers, or authorized dispensers with product-specific, FDA-approved "medication guides," or the means to produce the medication guides. *Id.* § 208.24(b). Distributors or packers receiving the medication guides from the manufacturer must provide them to the authorized dispensers (e.g., pharmacies) along with the shipment of the drug. *Id.* § 208.24(c). Each authorized dispenser is then responsible to provide a medication guide to each patient when the

prescription is filled.[1] *Id.* § 208.24(e). The medication guide is based on the approved prescribing information and must receive prior FDA approval before distribution. *Id.* §§ 208.20(a)(2), 208.24(a).

In creating these regulations, FDA stated that it "d[id] not believe that this rule would adversely affect civil tort liability" because the medication guide for patients "does not alter the duty, or set the standard of care for manufacturers, physicians, pharmacists, and other dispensers[,]" and because "courts have not recognized an exception to the 'learned intermediary' defense in situations where FDA has required patient labeling . . . ." Final Rule, *Prescription Drug Product Labeling; Medication Guide Requirements*, 63 Fed. Reg. 66378, 66383-84 (Dec. 1, 1998).

B. Factual and Procedural Background

Petitioner alleges that Johnny F. McDaniel's ("McDaniel") physician prescribed amiodarone to treat his atrial fibrillation, a use not approved by FDA. *Id.* 47a. McDaniel died on July 22, 2015, allegedly from pulmonary injury caused by amiodarone. *Id.* 52a-53a. Petitioner sued respondent, the alleged manufacturer of the amiodarone, in the United States District Court for the Western District of Tennessee, alleging that respondent violated FDA regulations by failing to provide the federally-required medication guide for amiodarone to distributors and pharmacies for dispensing to McDaniel with his prescription. *Id.* 47a-52a. The medication guide for patients warns of a risk of

[1] The petition incorrectly states multiple times that respondent was required to ensure that the decedent received the medication guide. Pet. 3, 4, 11, 15.

pulmonary toxicity (as does the labeling for health care providers). *Id.* 63a. Had McDaniel received the medication guide from the pharmacy, petitioner alleges, he would not have taken amiodarone and would have avoided the injury that caused his death. *Id.* 49a.

The complaint contains contradictory claims. It alleges that the warnings for amiodarone were adequate but not provided to the pharmacy for distribution to McDaniel, and also that the content of the warnings was inadequate.[2] *Id.* 49a-51a, 53a-54a, 56a-59a.

Respondent moved to dismiss arguing, *inter alia,* that petitioner's claims based on the alleged failure to provide the medication guide are impliedly preempted under *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 352-53 (2001), and 21 U.S.C. § 337(a)[3],

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[2] Among these contradictory allegations, petitioner alleges that the warnings to health care providers were not adequate (in an apparent effort to avoid the learned intermediary doctrine), while alleging at the same time that the warnings in the medication guide *were* adequate. This makes no sense because, under federal law, the medication guide warnings must be based on the health care provider warnings and all of the warnings must match exactly the labeling of the brand-name drug. The district court properly dismissed allegations that McDaniel's physician was misled as factually insufficient and petitioner did not appeal that finding.

[3] The FDCA expressly prohibits any private right of action and places sole authority for enforcement of its provisions in the United States. 21 U.S.C. § 337(a). As a result, state-law claims that "exist solely by virtue of [FDCA] requirements" or for which "the existence of these federal enactments is a critical element" are impliedly preempted because the claims "would exert an extraneous pull on the scheme established by Congress[.]" *Buckman*, 531 U.S. at 352-53.

and any claim challenging the content of the warnings for a generic drug is preempted by *Mensing*. Petitioner then clarified in her opposition to the motion to dismiss that she was not challenging the "adequacy" or "content" of the warnings, only the "failure of Upsher-Smith to fulfill its federally mandated responsibility to ensure Medication Guides are available for distribution directly to patients with each prescription." Resp. App. 12a; Pet. App. 8a.

The district court determined that the requirement to make medication guides available for distribution to patients exists only in regulations under the FDCA, and state-law claims premised on violations of the FDCA are preempted because FDA has the exclusive power to enforce the FDCA. Pet. App. 87a-89a, 92a. The court held that petitioner had not identified any parallel duty to provide a medication guide under Tennessee law. *Id.* 92a.

The Sixth Circuit affirmed in a split decision. The panel majority found that petitioner was seeking to enforce 21 C.F.R. § 208.24, the federal regulation requiring drug manufacturers to ensure the availability of medication guides for dispensing to patients. *Id.* 5a-14a. Although petitioner cited no Tennessee law in her complaint (or in any of her district court briefing), the panel majority found that her failure-to-warn claims are governed by the Tennessee Products Liability Act ("TPLA") and the TPLA "does not create a parallel duty to provide a Medication Guide." *Id.* 8a-9a.

The dissent concluded that petitioner pleaded a violation of the federal regulation only to avoid impossibility preemption under *Mensing*, and that her claims were based on an independent duty to warn

under Tennessee law (although the dissent cited no Tennessee authority imposing a duty to provide a medication guide). *Id.* 17a. Both of these grounds tracked arguments petitioner made for the first time on appeal, only after the district court held that a claim based on the federal medication guide regulation is preempted.

REASONS FOR DENYING THE PETITION

I. The Decision Below Does Not Implicate Any Circuit Split

The petition seeks review of a question—whether a state-law, failure-to-warn claim that parallels a defendant's failure to follow FDA labeling regulations is impliedly preempted—that is not presented by the Sixth Circuit's decision. Rather, the Sixth Circuit and district court below found preemption because petitioner expressly pleaded that her claims are premised on the alleged failure to distribute the FDA-mandated medication guide for dispensing to patients as required by federal regulation, as to which Tennessee law has no parallel requirement (and 21 U.S.C. § 337(a) prohibits petitioner from privately enforcing this regulation). Pet App. 5a-14a, 92a. The circuit courts are actually not in disagreement with these decisions, or as to whether state-law claims that parallel federal requirements are preempted under *Buckman*. Indeed, the Sixth Circuit is the *only* circuit court to address preemption of such claims involving the federal medication guide regulation.

The cases petitioner cites show no conflict with the panel's decision. In *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013), for example, Allergan alleged that Athena violated the California

Health Code by marketing its hair and eyelash growth products without an approved new drug application. *Id.* at 1353. Athena argued that the claim was preempted because it was based on a California law that simply incorporated FDCA provisions and therefore was "not rooted in state law tort principles." *Id.* at 1354-55. But the California Health Code's incorporation of various FDCA provisions meant that California law "parallel[ed]" federal law and the claim did not exist "solely by virtue of the FDCA . . . requirements." *Id.* at 1354, 1356. Here, on the other hand, Tennessee has not incorporated FDA's medication guide requirements into its law.

Petitioner's reliance on *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), as creating a split is also misplaced. There, the plaintiff alleged that a hip implant FDA found to be "adulterated" because it failed to comply with federal standards was defectively manufactured under Illinois tort law. *Id.* at 549. Unlike in *Buckman*, the plaintiff had alleged "breach of a well-recognized duty owed to her under state law—the duty of a manufacturer to use due care in manufacturing a medical device." *Id.* at 558. Evidence that the implant was "adulterated" under federal law was relevant to proving a manufacturing defect under state law. *Id.* at 557. In contrast to *Bausch*, there was no breach of a "well-recognized" state-law duty here—or any state-law duty for that matter—because there is no duty under Tennessee law to distribute a medication guide.

Bausch is similar to *LeFaivre v. KV Pharm. Co.*, 636 F.3d 935 (8th Cir. 2011). In *LeFaivre*, the plaintiff brought claims for breach of implied warranty of merchantability and violation of Missouri's consumer

protection law against a pharmaceutical manufacturer to recover economic loss resulting from his purchase of drugs manufactured without proper quality control procedures. *Id.* at 937. The manufacturer had already agreed the drugs were adulterated and some misbranded, and had issued a recall and agreed to destroy its remaining stock of adulterated drugs. *Id.* Unlike here, LeFaivre's claim was a traditional state-law claim in that he alleged the recalled medication he bought was "unmerchantable" and thus violated state warranty and consumer protection law. *Id.* at 937-38.

McClellan v. I-Flow Corp., 776 F.3d 1035 (9th Cir. 2015), is not contrary to the Sixth Circuit's decision either. As petitioner points out, negligence per se is not at issue here. Even so, the negligence per se jury instruction in *McClellan* was not preempted because "[t]he failure-to-warn claims McClellan alleged did not arise solely by virtue of the [FDCA]." *Id.* at 1040-41 (citing *Buckman*, 531 U.S. at 352-53). Here, petitioner's claim for failure to distribute a medication guide *did* arise solely from federal regulations. Pet. App. 5a-8a.

Finally, the Fifth Circuit decisions petitioner cites do not create a circuit split. In *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), the plaintiff alleged that the manufacturer's warnings were inadequate because it had substantially underreported the number of injuries occurring with the medical device. *Id.* at 765-67. The manufacturer's alleged failure to submit adverse event reports to FDA in accordance with federal regulations was evidence that the labeling was inadequate, which is a "recognized state tort claim[.]" *Id.* at 775. In contrast,

petitioner disclaimed any allegations that the manufacturer's warnings were inadequate in the district court, clarifying that her complaint was respondent's failure to provide a medication guide to its distributor to include with the medication shipment to McDaniel's pharmacy—a requirement that exists solely under the FDCA. Pet. App. 6a-8a.

And the dicta petitioner cites from *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674 (5th Cir. 2014), indicating that failure to provide FDA-approved warnings to the plaintiff or his physician would violate Texas law and federal law, is not contrary to the Sixth Circuit's decision. It reflects only that the *Eckhardt* panel apparently concluded, albeit incorrectly, that in prescription drug cases, Texas law imposes a duty for manufacturers to warn *patients*, not just health care providers. Even if that were true, this case does not involve Texas law.

Petitioner notes that district courts have reached different conclusions on whether claims alleging violations of the medication guide regulation are preempted. But no court has ruled against preemption based on an alleged failure to provide a medication guide under Tennessee law, and this Court does not ordinarily review a difference of opinion among district courts. S. Ct. R. 10.

II. The Petition Does Not Present an Important Question Warranting the Court's Review

The petition does not present an important question meriting this Court's review of the Sixth Circuit's decision. Petitioner argues that courts of appeals and district courts "will continue to struggle with the question presented[.]" Pet. 19. The evidence

so far in the circuit courts is to the contrary. Petitioner's counsel has already appealed similar preemption decisions in at least two other amiodarone medication guide cases. Both times the court of appeals failed to reach the preemption question, affirming the dismissals on learned intermediary doctrine grounds; namely, that the duty to warn applicable to prescription drugs is as to the prescribing health care provider, not to patients. *See Bean v. Upsher-Smith Pharms., Inc.*, 765 F. App'x 934 (4th Cir. 2019); *Tutwiler v. Sandoz, Inc.*, 726 F. App'x 753 (11th Cir. 2018).[4]

III. The Decision Below Correctly Found That Federal Law Preempts Claims Premised on a Violation of Federal Regulations With No Basis in State Tort Law

The court of appeals correctly determined that petitioner's claims were impliedly preempted. As the court explained, the decision was driven by petitioner's specific pleadings and arguments; it was not an inconsistent application of *Buckman*.

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[4] The dissent views the learned intermediary doctrine in Tennessee as an affirmative defense rather than a common-law rule that defines to whom a manufacturer owes the duty to warn in prescription drug cases. Pet. App. 19a-20a. The dissent's view is contrary to the Tennessee Supreme Court. *See Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) ("In dispensing 'ethical or prescription' drugs all warnings relating to the use of the drug must be given to the doctor or physician prescribing the drug."); *id.* at 431 ("The Upjohn Company's warnings and instructions to prescribing physicians were sufficient to discharge its duty to those persons to whom it owed a duty to warn.").

Petitioner made clear that her claims are premised solely on violation of the federal medication guide regulation, not traditional state tort law. For example, the complaint alleges that failure to provide the medication guide was "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"; that Upsher-Smith "was responsible by federal regulation for ensuring that the appropriate warning labels and Medication Guides were provided to McDaniel"; and that "Upsher-Smith did not provide the Medication Guide to the distributors for distribution to [McDaniel] by his pharmacists as required by the FDA[.]" Pet. App. 6a-7a.

The complaint does not identify any provision of Tennessee law that petitioner considered "parallel" to the federal medication guide regulation. In fact, the complaint does not refer to Tennessee law at all.[5] Neither did petitioner's district court briefing opposing preemption. To the contrary, as the panel majority noted, petitioner's opposition to the motion to dismiss "doubled down on her reliance on the FDA regulations[,]" arguing 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 Medication Guides are available for distribution

[5] The petition therefore is incorrect when it contends that the complaint asserts claims under Tennessee law that "mirror[] a violation of federal FDA regulations." Pet. 1-2.

directly to patients with each prescription." *Id.* 8a; Resp. App. 12a.

The panel majority likewise properly rejected arguments petitioner raised about Tennessee law for the first time on appeal. Pet. App. 8a-9a ("McDaniel cannot salvage her appeal by hanging her hat on a generic duty to warn under Tennessee law."). The panel majority discussed at length petitioner's failure-to-warn claim under the TPLA, finding that decisions applying the TPLA in failure-to-warn cases were of "no help" to petitioner because she "pleaded that the 'adequacy' of warnings . . . is not the issue; the issue is Upsher-Smith's alleged failure to ensure the Medication Guide's availability for distribution." *Id.* It properly concluded that the "TPLA does not create a parallel duty to provide a Medication Guide." *Id.* 9a.

The panel majority also was correct in rejecting petitioner's newly-discovered and rather transparent argument on appeal that she had alleged a violation of the federal medication guide regulation "strictly to avoid impossibility preemption under [*Mensing*]." *Id.* 12a. *Mensing* held that claims alleging inadequacy of the warnings for a generic drug are preempted because generic manufacturers must maintain the same warnings as the brand-name drug. 564 U.S. at 613. But petitioner clarified in the district court that she was not challenging the *content* of the warnings, only that McDaniel did not receive the medication guide from the pharmacy with his prescription. *Mensing*, therefore, was inapposite, and the panel

majority rightly labeled this argument "a red herring."[6] Pet. App. 13a.

Petitioner's reliance on the post-*Mensing* decision in *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), is likewise misplaced. The *Fulgenzi* court held that the plaintiff's Ohio tort claim was not preempted because it was premised on an independent state-law duty to provide adequate warnings and the manufacturer's failure to revise its labeling rendered the labeling inadequate under Ohio law. *Id.* at 586-87. The court also found that this claim would stand on its own without regard to the manufacturer's federal duties. *Id.* at 587. In contrast, petitioner here could only cite to the federal medication guide regulations in support of her failure-to-warn claims; she expressly admitted that the adequacy of the warnings was not at issue. Pet. App. 6a-8a. The panel majority also found the *Fulgenzi* claims and analysis diverse from those of petitioner. Pet. App. 11a-13a ("We won't ignore the language of McDaniel's allegations simply so that we may shoehorn her claims into *Fulgenzi*'s realm.").

The petition notes that this Court has described *Buckman* as being concerned with a "uniquely federal area of regulation" and state-law claims that would interfere with "the operation of a federal program." Pet. 23 (citing *Chamber of Commerce of the United*

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[6] Petitioner told the district court that *Mensing* would only preempt claims challenging the *content* of the medication guide—claims she clarified to the district court she was *not* making. Resp. App. 11a-12a. Accordingly, for petitioner to turn around and tell the court of appeals and this Court that she *had* to plead a violation of the federal regulation to avoid *Mensing* preemption is simply not credible.

States v. Whiting, 563 U.S. 582, 604 (2011)). That is precisely why these claims are preempted. FDA's medication guide program *is* "uniquely federal." It has no state-law counterpart. State-law claims that "exist solely by virtue of [FDCA] requirements" or for which "the existence of these federal enactments is a critical element" are impliedly preempted because the claims "would exert an extraneous pull on the scheme established by Congress[.]" *Buckman*, 531 U.S. at 352-53. Moreover, FDA never intended the program to alter the duty or set the standard of care for a manufacturer under state law. 63 Fed. Reg. at 66384.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

CARY SILVERMAN
Counsel of Record
SHOOK HARDY & BACON L.L.P.
1800 K Street, NW, Suite 1000
Washington, DC 20006
(202) 783-8400
csilverman@shb.com

MARK C. HEGARTY
DOUGLAS B. MADDOCK, JR.
SHOOK HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, Missouri 64108

Counsel for Respondent

JUNE 22, 2020

APPENDIX

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[ENTERED: Sept. 21, 2016]

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.	)	

PLAINTIFF'S RESPONSE IN OPPOSITION TO DEFENDANT UPSHER-SMITH PHARMACEUTICAL, INC.'S MOTION TO DISMISS COMPLAINT

COMES NOW the Plaintiff in the above-captioned case, and in response to Defendant Upsher-Smith Pharmaceuticals, Inc.'s Motion to Dismiss Plaintiff's Complaint and states as follows:

I. INTRODUCTION

The Complaint in this action was filed on July 21, 2016. This Memorandum in Opposition is in response to Upsher-Smith Pharmaceuticals, Inc.'s (hereinafter "Upsher-Smith" or "Defendant") Motion to Dismiss

Complaint filed on August 22, 2016. This response is timely filed on September 21, 2016.

McDaniel's Complaint alleges common-law negligent failure-to-warn claims based on Upsher-Smith's failure to provide the FDA required Medication Guide to Johnny McDaniel. McDaniel further alleges that Upsher-Smith negligently misrepresented amiodarone as being safe for off-label uses such as the inherently dangerous first-line treatment of atrial fibrillation. McDaniel also alleges that Upsher-Smith failed to adequately warn the medical community, including Dr. James Litzow, Johnny McDaniel's physician.

Rita McDaniel's Complaint meets the federal pleading standards, presents plausible claims that travel beyond speculation and provides a framework for relief. The allegations present claims that are not pre-empted by federal regulatory schemes. Upsher-Smith's Motion to Dismiss McDaniel's Complaint should be denied and discovery commenced. In the alternative, Rita McDaniel should be allowed to amend the Complaint as may be required by the Court.

II. STATEMENT OF THE ISSUES

A. Whether the allegations in the Complaint, if accepted as true, are plausible, rise above speculation and provide the right to relief.

B. Whether McDaniel's claims regarding Upsher-Smith's negligent failure to warn and negligent off-label promotion of amiodarone remain in light of *Pliva, Inc. v. Mensing* and

its progeny. (*Pliva, Inc. v. Mensing*, 564 U.S., 131 S.Ct. 2567 (2011) *reh'g denied*).

C. Whether the rulings of other District Courts support McDaniel's efforts to be heard on the merits.

D. In the alternative, whether McDaniel should be allowed to amend and file a second amended complaint.

III. STATEMENT OF THE CASE

Plaintiff McDaniel's (hereinafter "Rita McDaniel", "McDaniel" or "the Plaintiff') Complaint was filed on July 21, 2016. Upsher-Smith's Motion to Dismiss the Complaint was filed on August 22, 2016. This response to that Motion to Dismiss is timely filed on September 21, 2016.

IV. STATEMENT OF THE COMPLAINT

Johnny McDaniel was diagnosed with atrial fibrillation. His condition was not deemed life threatening. Johnny McDaniel did not have ventricular tachycardia and was never in a medical situation of "last resort" as to the management of his atrial fibrillation. (COMPLAINT ¶ 34).

Beginning in May of 2015 and continuing on through June of 2015, Dr. James Litzow prescribed a course of 200 mg amiodarone tablets for treatment of Johnny McDaniel's non-life threatening atrial fibrillation. McDaniel filled the prescription and ingested the drug amiodarone according to the

instructions.[1] (COMPLAINT ¶ 34). Johnny McDaniel was not aware that his use of the drug was "off-label." He was not provided the Medication Guide warnings as required by the FDA. (COMPLAINT ¶¶ 34-40).

In the Spring of 2015, Johnny McDaniel began to experience many of the symptoms outlined in the Medication Guide, including shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. (COMPLAINT ¶¶ 43-45). McDaniel's condition continued to deteriorate. He experienced increasing pulmonary issues to include shortening of breath, deep cough and difficulty in living the active life that he always enjoyed. Johnny McDaniel passed away with a diagnosis of interstitial pneumonia/lung disease on July 22, 2015. (COMPLAINT ¶¶ 44-45).

Johnny McDaniel was not aware that his use of the medication was for an off-label use and he clearly was not in a situation of last resort as to his atrial fibrillation. He was not aware of the improper promotion of amiodarone to the medical community including his physician for the off-label use of amiodarone. The amiodarone Johnny McDaniel ingested was manufactured and marketed by Upsher-Smith.[2] Johnny McDaniel did not receive the FDA required Medication Guide prior to ingesting amiodarone and was not aware of the warnings in the Medication Guide. Johnny McDaniel experienced the serious and life changing side effects outlined in the Medication Guide. The Medication Guide that Johnny

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[1] Naval Branch Health Clinic

[2] *Id.*

did not receive was required by federal law to be provided to Johnny McDaniel with each prescription, outside the interaction with his doctors and would have warned him of the dangers of amiodarone use for atrial fibrillation. (COMPLAINT ¶¶ 34-41).

V. SUMMARY OF THE ARGUMENT

The requirements of a well-pleaded complaint are clear. The allegations in the complaint must be accepted as true and construed in a light most favorable to McDaniel. The allegations in McDaniel's Complaint are plausible, rise above mere speculation and provide McDaniel a right to relief.

Allegations in the Complaint relative to the state law negligence claims include Upsher-Smith's improper promotion of the off-label use of amiodarone for atrial fibrillation as well as the negligent failure of Upsher-Smith to provide for the distribution of the required Medication Guide warnings. The claims alleged are viable claims and are not pre-empted by federal law.

In the alternative, McDaniel, should be allowed to further develop additional facts and prepare and file an amended complaint.

VI. ARGUMENT

A. The allegations in the Complaint, if accepted as true, are plausible, rise above speculation and provide the right to relief.

The purpose of Federal Rule 12(b)(6) is to adequately "test the legal sufficiency of a claim."

Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001); *Keys v. Humana, Inc.*, 684 F.3d 605, 115 Fair Empl.Prac.Cas. (BNA) 588 (6th Cir., 2012); *Giarratano v. Charlesson*, 521 F.3d 298, 302 (4th Cir. 2008). To survive dismissal for failure to state, a claim a complaint must contain more than mere "labels and conclusions" or a simplistic "formulaic recitation of the elements of a cause of action." The operative complaint must contain factual allegations sufficient to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

While "a complaint need not contain detailed factual allegations ...it must plead 'enough facts to state a claim to relief that is plausible on its face.'" (*Id.* at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Igbal*, 556 U.S.662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 556).

Plausibility requires "more than a sheer possibility that a defendant has acted unlawfully." *Twombly*, 550 U.S. at 555. When analyzing a complaint for failure to state a claim under Rule 12(b)(6), "[a]ll allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party." *Smith v. Jackson*, 84 F.3d 1213, 1217 (9th Cir.1996). When ruling on a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6), all factual allegations in the complaint must be accepted as true, with all reasonable inferences construed in the light most favorable to the plaintiff. *Wagner v. Daewoo Heavy Industries America Corp.*, 289 F.3d 1268, 1270 (11th Cir. 2002). The analysis is

a "context-specific" task. *Francis v. Giacomelli*, 588 F.3d 186 (4th Cir., 2009). "If a reasonable court can draw the necessary inference from the factual material stated in the complaint, the plausibility standard has been satisfied." *Keys v. Humana, Inc.*, 684 F.3d 605, 115 Fair Empl.Prac.Cas. (BNA) 588 (6th Cir., 2012); *See also Simmons v. Sonyika*, 394 F.3d 1335, 1338 (11th Cir. 2004); *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); Jackson v. Okaloosa County, Fla., 21 F.3d 1531, 1534 (11th Cir. 1994).

Here the Complaint presents plausible claims and is sufficient for the purposes of surviving a Rule 12(b)(6) challenge. The facts alleged are specific and more than "formulaic statements." Included are details concerning Johnny McDaniel's medical situation, his specific injury, information concerning the "off-label" use of amiodarone, Upsher-Smith's failure to provide for distribution of the required Medication Guide and its warnings resulting in the distribution of a misbranded drug. Details concerning the improper sales and marketing of the product to the medical community including Johnny McDaniel's physician, for uses other than "last resort" ventricular arrhythmias, are also alleged. Upsher-Smith's knowledge of other incidents of the specific type of injury suffered by Johnny McDaniel as well as Upsher-Smith's concealment of information related to pulmonary toxicity are also included in the Complaint. (COMPLAINT ¶¶ 34-42).

Johnny McDaniel was prescribed and ingested amiodarone for his atrial fibrillation, a medical condition that was not life threatening. His prescription was undeniably for a dangerous and warned against off-label use: atrial fibrillation.

(COMPLAINT ¶¶ 32-34). The amiodarone tablets Johnny McDaniel received and ingested were manufactured, marketed and distributed by Upsher-Smith. Upsher-Smith's drug is the generic version Wyeth's brand name amiodarone drug. (COMPLAINT ¶ 35).

Complying with FDA requirements for a "package insert," or a bottle-warning label does not discharge Upsher-Smith's duty to McDaniel; this dangerous drug has a much different requirement. Upsher-Smith must ensure distribution of a Medication Guide, with language and design approved by the FDA, directly to each patient with each and every prescription. The Medication Guide is provided outside of the in-office interaction with the physician and in addition to the package inserts and other warnings. Failure to provide a Medication Guide renders the drug "mislabeled."

Selling mislabeled drugs is per se illegal. The sell of illegal drugs is not only a crime, but leads to civil liability. McDaniel's claims are viable under Tennessee law and are not "preempted" by federal law because the claim is brought as a specific and documented result of the Upsher-Smith's negligent failure to follow FDA-mandated requirements; requirements that render the sale of the product illegal when not followed. (COMPLAINT ¶ 41).

Johnny McDaniel did not receive the Medication Guide required by federal law. The Medication Guide program is an essential element of the FDA's effort to provide life saving safety information directly to Johnny McDaniel and outside of his interaction with his physician. The Medication Guide would have informed Johnny that the use was off-label and

warned him of the serious side effects of amiodarone, many of which he experienced prior to his death. (COMPLAINT ¶ ¶ 35-42). Each manufacturer of a drug for which a Medication Guide is required is responsible under federal law for ensuring that the Medication Guides are available to the distributor in sufficient quantity to ensure distribution directly to patients with each prescription dispensed. The Complaint clearly alleges Upsher-Smith's negligent failure to provide for the distribution of the mandated Medication Guide to Johnny McDaniel. The Medication Guide includes risk information important to patients such as Johnny and it is identified as an important component of the product labeling process. (COMPLAINT I 39-42). Only additional discovery can reveal exactly how and where Upsher-Smith's marketing and distribution process failed Johnny McDaniel.

Upsher-Smith participated in and greatly benefited from the long-term promotion and off label marketing of the amiodarone that Johnny McDaniel ingested. (COMPLAINT ¶ 5). The actual, physical negligent failure to provide the warnings highlighted in the Medication Guide concealed material information from Johnny McDaniel and his family. Important information Johnny did not receive that was key to his health and safety. (COMPLAINT ¶¶ 39-42). Upsher-Smith failed to exercise its duty of due care to Johnny McDaniel; a foreseeable user of the product. (COMPLAINT ¶ 68).

The Court must view the pleaded allegations as true and construe all inferences in favor of the plaintiff. "The court, in considering the motion, must take all allegations of the Complaint that the

defendant does not contest as true, and, where the parties' affidavits conflict, the court must construe all reasonable inferences in favor of the plaintiff." *Huey v. Am. Truetzschler Corp.*, 47 F. Supp. 2d 1342, 1344 (M.D. Ala. 1999) (citing *Madara v. Hall*, 916 F.2d 1510, 1514 (11th Cir. 1990)). A motion to dismiss is only granted when the movant demonstrates beyond doubt that the plaintiff can prove "no set of facts in support of his claim which would entitle him to relief." *Harper v. Blockbuster Entm't Corp.*, 139 F.3d 1385, 1387 (11th Cir.1998) (internal quotations omitted). *See also Ctr. For Bio—ethical Reform Inc. v. Napolitano*, 648 F.3d 365 (6th Cir., 2011); The operative complaint must contain factual allegations sufficient to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

Johnny McDaniel's claims as outlined in the complaint are plausible. The right to relief is beyond speculation. The Motion to Dismiss must be denied.

B. <u>The allegations of the state law claims in the complaint, if accepted as true, are not pre-empted by federal law and do not fail under a *Mensing* analysis.</u>

Upon obtaining counsel, Rita McDaniel filed this Tennessee negligence action. Federal courts "have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. at 485. This presumption against preemption is especially forceful when "Congress has `legislated ... in a field which the States have traditionally occupied,' " and courts will " `start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act

unless that was the clear and manifest purpose of Congress.' " *Id*. (Citations omitted). States have always been concerned with protecting their citizens from inherently dangerous products, and their common law has served as a method of recourse for those injured by such products. *See Lohr*, 518 U.S. at 475.

McDaniel's claims clearly articulate and allege recognized state law claims. The Complaint includes supporting factual allegations related to the "off-label" use and the negligent failure to provide for the distribution of required warnings in violation of federal rules and regulations. Allegations that clearly negate federal preemption, including the sale of a mislabeled drug, are the gravamen of McDaniel's Complaint.

Recent rulings on the preemption issue by the United States Supreme Court do not provide a safe harbor for Upsher-Smith, *See generally Pliva, Inc. v. Mensing*, 564 U.S.131 S.Ct. 2567 (2011) *reh'g denied and Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013). *Mensing* dealt specifically with on-label warnings; not Medication Guides. There the Supreme Court confirmed the primacy of the federal regulation and the inability of a generic manufacturer to change the wording and format of the federally dictated labeling of the brand manufacturer. *Pliva, Inc. v. Mensing*, 564 U.S.131 S.Ct. 2567 (2011), (*reh'g denied*).

In *Bartlett* the Supreme Court confirmed that state law claims, which turn on the adequacy of a particular drug's warnings, are preempted by the federal regulatory scheme. There the Court noted that a manufacturer couldn't be required to simply cease

acting to avoid liability. The focus there was again on warning content and not the negligent failure to distribute the Medication Guide; a state claim as articulated in McDaniel's complaint. *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013).

Here the allegations in the Complaint are that Upsher-Smith engaged in, supported and benefitted from "off-label" promotion and failed to actually and physically provide for the appropriate distribution of federally mandated warnings in the form of the Medication Guide. (Complaint ¶¶ 35-42). 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 Medications Guides are available for distribution directly to patients with each prescription. (Complaint ¶¶ 35-42); *See also* 21 C.F.R. 208.

A similar result has been reached in addressing a Motion to Dismiss in the amended complaint of another bad drug case. In *Whitener v. PLIVA, Inc.*, a more on-point pharmaceutical case involving a generic manufacturer, the District Court of the Eastern District of Louisiana distinguished *Mensing* with similar reasoning. *Whitener v. PLIVA, Inc.*, No. 10-1552 Section "L" (4), 2012 WL 3948797 (E.D. La. June 4, 2012). In the analysis, the court noted that to nullify preemption, it was sufficient that the plaintiff simply "set forth sufficient information to outline the elements of his claim or to permit inferences to be drawn that these elements exist." *Walker v. South Cent. Bell Tel. Co.*, 904 F.2d 275, 277 (5th Cir.1990)

(quoting Wright & Miller, 5 Fed. Pract. & Proc. Civ. § 1216 (1st ed.)) *Whitener v. PLIVA, Inc.*, Not Reported F.Supp.2d (2012) 2012 WL 3948797).

The *Whitener* court further noted:

> However, Defendant simply has not managed to overcome the fundamental distinction between this case and *Mensing*: unlike in *Mensing*, Plaintiff in this case do not allege that Defendant should have changed the contents of the label in violation of federal law. Instead, they allege that Defendant simultaneously violated *both* state *and* federal law by actively engaging in off-label promotion despite known risks not listed on the label.

Id. at p 9.

McDaniel's Complaint notes in pertinent part that Upsher-Smith ultimately deceived the physicians, pharmacists, and consumers into believing that prescribing and taking amiodarone off-label for atrial fibrillation was appropriate even though Upsher-Smith knew FDA approval had not been granted for those uses and, moreover, there was significant medical-scientific evidence suggesting amiodarone was very dangerous in those situations. So serious in fact, to result in serious pulmonary illness, toxicity, and death, when so used. (COMPLAINT ¶16). The complaint specifically addresses the impact of Upsher-Smith's actions as to the prescribing physician and causation. (COMPLAINT ¶¶ 32-42).

Granted, additional discovery is clearly required to develop important facts, but only a reasonable amount of common sense is required to understand that any product requires some level of promotion if it is to enter into the stream of commerce. Products,

whether brand or generic, do not magically make their way to an end user without some form of promotion; whether that promotion is the Defendant's website with product description and information that omits appropriate warnings, general company promotion of itself as a purveyor of safe generics, peer to peer activities or other forms of promotion sufficient and specific to result in a prescription to Johnny McDaniel. The fact that the Upsher-Smith loudly and often describes any and all allegations by McDaniel as inadequate does not make it so. McDaniel's allegations are sufficient for the purposes of the Complaint and can be tested against the evidence to be developed in discovery.

The Complaint clearly alleges that the FDA has instituted a specific program to ensure that the important and lifesaving warnings concerning the prohibition of amiodarone use for atrial fibrillation must be provided directly to Johnny McDaniel. There is no other reason for the development of the Medication Guide program and no other reason for that program to direct that the manufacturer ensure that the Medication Guide is placed directly in the hands of the patient outside of the face-to-face interaction with the prescribing physician. (COMPLAINT ¶¶ 40-42).

The very short list of drugs subject to the Medication Guide program includes those drugs, such as amiodarone, that cause "serious adverse effects." The Complaint quotes the FDA regulation in pertinent part and notes that 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 produc*t, or patient adherence to directions for the use of a product are essential to its effectiveness." *Id*. (emphasis added). It is clear and alleged in the Complaint that the purpose of the Medication Guide is to provide information and warnings directly to Johnny McDaniel. Information and warnings he did not receive due to the negligence of Upsher-Smith. *Id*.

McDaniel does not allege that the contents of the labeling should have been changed. More specifically and importantly, McDaniel alleges that the Medication Guide and its warnings were not provided to him in accordance with the FDA mandate. The allegations of state law claims in the Complaint as related to the Upsher-Smith's promotion of an "off-label" use and its negligent failure to ensure the proper distribution of the Medication Guide are not preempted by federal law. Genuine material factual issues remain to be developed. The drug is clearly not suitable for the specific purpose of alleviating atrial fibrillation without horrific consequences. The Complaint includes allegations that Upsher-Smith misrepresented the risks associated with amiodarone and encouraged physicians to prescribe the drug for off label uses. The allegations of the Complaint are plausible and more than sufficient for the purposes of this action.

The Complaint clearly alleges sufficient connections between the conduct of Upsher-Smith and Johnny McDaniel's injury. Upsher-Smith may want more specificity, and will surely get more as the facts are developed, but at this stage, the allegations are

adequate to preserve McDaniel's claims and allow the opportunity to develop the facts. The allegations relative to causation are sufficient. Nothing more is required at this stage of the litigation.

The Complaint contains sufficient factual allegations to "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Igbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citing *Twombly*, 550 U.S. at 556). McDaniel's claims are more than speculative and include factual content in the form of references to the warning letters to the Defendant from the FDA addressing the issues. (COMPLAINT ¶¶ 41-42).

McDaniel's claims are certainly plausible. The Complaint contains allegations that are more than sufficient relative to this stage of the litigation. This is not a motion for summary judgment. Dismissal in accordance with Rule 12(b)(6) is not appropriate. The Motion to Dismiss should be denied.

C. Whether the rulings of District Courts in other jurisdictions support McDaniel's efforts to be heard on the merits.

All of the recent fact similar cases Upsher-Smith cites are factually inapposite, and—with respect to most of the cases cited—Upsher-Smith appears to misconstrue their legal holdings. In *Stephens v. Teva*

Pharmacy[3], for instance, the court held that some of the plaintiff's failure-to-warn claims were preempted by federal law, but only because, unlike in this case, the plaintiff's desired warning would have required the defendant to violate its duty of sameness. *Stephens v. Teva Pharmacy* 70 F. Supp. 3d 1246, 1253 (N.D. Ala. 2014) (quoting *Strayhorn v. Wyeth Pharmaceuticals, Inc.*, 737 F.3d 378, 391-392 (6th Cir. 2013)) (noting that *Mensing* preempts "claims that are, at their core, claims that the generic manufacturer failed to provide additional warnings *beyond that which was required by federal law* of the brand-name manufacturers.") (emphasis added).

Judge Johnson in *Stephens* rejected the plaintiffs claims regarding the Medication Guide, not because of *Mensing*, but rather because the plaintiff in *Stephens* had not alleged that the defendant failed to provide Medication Guides to the pharmacy. *Id.* at 1252. By contrast, in this case, McDaniel not only alleged that Upsher-Smith failed to provide sufficient Medication Guides to the pharmacy where Johnny McDaniel filled his prescriptions, but also that the Medication Guides were not provided by Upsher-Smith to the distributors and pharmacists for distribution to McDaniel with his prescription. Because he did not receive the Medication Guide, Johnny McDaniel received and ingested a mislabeled drug.") (emphasis added). To put it simply, McDaniel has alleged *different* wrongful acts in this case from the wrongful acts alleged by the plaintiff in the *Stephens case.*

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[3] Plaintiff in the *Stephens* and the *Connolly* case made independent decisions not to pursue an appeal.

Contrast Stephens, 70 F. Supp. 3d at 1250 *with* (COMPLAINT ¶ 34-42).

In *Dreher*, another Northern District of Alabama case, the court, like the *Mensing* Court, held only that the plaintiff's failure-to-warn claims that created "impossibility" for the defendant, were preempted by federal law. *Dreher v. Wyeth Pharm., Inc.*, No. 2:14-CV-00280-KOB, 2015 WL 3948961, at *4 (N.D. Ala. June 29, 2015). The *Dreher* court also dismissed some of plaintiff's claims against the generic defendants *without prejudice* based on pleading deficiencies—not *Mensing*. *Id*. at *8. The *Dreher* case continues in the Northern District of Alabama as to remaining claims.[4]

McDaniel's Complaint more than meets the pleading standards set by Rule 8. *See Fed.R.Civ.P Rule 8*. In the *Dreher* case, the court believed the plaintiff was apparently seeking to enforce FDA regulations. Here, by contrast, McDaniel articulates clear state law tort claims, using Upsher-Smith's violations of FDA regulations to demonstrate negligence under *state* law. *See Cabiroy v. Scipione*, 767 A.2d 1078, 1081 (Pa. Super. Ct. 2001) (noting that, under state law, FDA regulations can be the basis of state law negligence per se claims). To reiterate, the only claims that the *Dreher* court dismissed based on the *Mensing* case have not been alleged in the current case. McDaniel alleges only that Upsher-Smith (1) negligently failed to follow federal safety requirements designed to protect McDaniel's

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[4] An additional factually similar case has been brought by the family of former University of Alabama Mal Moore, and continues in the Northern District of Alabama. (NDAL — 2:15-cv-00529-MHH)

interests and (2) violated state law duties that do not conflict with federal law. (COMPLAINT ¶¶ 30-42).

The *Rusk v. Wyeth-Ayerst Laboratories* case in the Western District of Texas is similar factually to the current case. There, Judge Yeakel ruled in the plaintiffs favor and has set the case for trial. *See Rusk v. Wyeth-Ayerst Labs., Inc.*, No. A-14-CV-00549-LY-ML, 2015 WL 3651434, at *4-*6 (W.D. Tex. June 11, 2015). In the *Rusk* case, the court held squarely that the claims made not preempted by *Mensing*. *See id*. at *5 (quoting *Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813, 819 (S.D. Ohio 2013) ("Nothing in the FDCA requires defendants to promote their drug for an off-label use, nor is the federal law otherwise at odds with the negligence, breach of implied warranty, and fraud claims brought by Plaintiff"); *id*. at *7 (noting, with respect to plaintiff's Medication Guide claim, that "such a claim would survive federal preemption" under the reasoning of a recent Fifth Circuit case). In response to the amended complaint there, Judge Yeakel has now narrowed the issue for trial to one issue focused squarely on the failure of Sandoz to provide the Medication Guide. The *Rusk* case is currently set for trial on one of the very claims that Sandoz asserts is preempted here.[5]

Judge Yeakel in accepting the magistrate judge's original recommendation in Rusk stated that "there is no allegation in the [c]omplaint . . . that the CVS that filled Mr. Rusk's prescription was unable to provide

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[5] Judge Yeakel's Orders adopting the recommendations of his magistrate judge are provided at EXHIBIT ONE and EXHIBIT TWO. Judge Lane's Report and Recommendations are provided at EXHIBIT THREE and EXHIBIT FOUR.

him a [m]edication [g]uide because Sandoz failed to supply one to CVS." *Id*. at *8. In the current case, by contrast, McDaniel alleges that McDaniel did not receive the Medication Guide from his pharmacist because the Defendant 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." (COMPLAINT ¶¶ 36; 41-42). Regardless, as even the authority cited by Sandoz makes clear, McDaniel's claims in this case are not preempted by the *Mensing* decision.

It is important to note that 21 C.F.R. 208 specifically requires the manufacturer to distribute Medication Guides in sufficient quantity to *ensure* distribution to the patient. In other words, the regulation enumerates a duty to not only provide a sufficient quantity of Medication Guides but also to have in place and maintain some process or protocol that makes absolutely sure the Mediation Guide gets in the hands of the patient with each prescription. The regulation makes it clear that the critical warnings contained in the guide must reach the patient with each prescription and in the proper form. *See generally* 21 C.F.R. 208. *Marvin v. Zydus Pharmaceuticals, Inc.*, a factually similar case in the Western District of Wisconsin against the generic amiodarone manufacturer, Zydus Pharmaceuticals, Inc., is also supportive. *Marvin v. Zydus Pharmaceuticals, Inc.*, WDWI-15-cv-749-bbc. There, Judge Crabb, with an Order supported by her well-reasoned Memorandum Opinion, ruled unequivocally that the plaintiffs claims as to negligence per se for

the defendant's failure to provide the mandated Medication Guide should go forward.[6]

The rulings of District Courts in other jurisdictions on cases with similar facts and parties support McDaniel's efforts to be heard on the merits. Those cases are either easily distinguished as above or fall squarely in McDaniel's favor.[7] Upsher-Smith's Motion to Dismiss is due to be denied.

D. In the alternative, McDaniel should be allowed to develop additional facts, and prepare and file an amended complaint.

Pursuant to Federal Rule of Civil Procedure 15 (a)(2), "a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires." The decision whether to grant leave to amend a pleading is within the sound discretion of the district court. *Nat'l Serv. Indus., Inc. v. Vafla Corp.*, 694 F.2d 246, 249 (11th Cir. 1982).

In *Bryant v. Supree*, the court noted that a District Court's discretion to dismiss a complaint without leave to amend is "severely restrict[ed] by Fed. Rule Civ. P. 15(a), which directs that leave to amend `shall be freely given when justice so requires.'" *Bryant v. Supree*, 252 F.3d 1161 at 1163 (11th Cir. 2001)(quoting *Thomas v. Town of Davie*, 847 F.2d 771, 773 (11th Cir. 1988) (Citation omitted). The Eleventh Circuit noted that amending the case previously is no

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[6] Judge Crabb's Opinion and Order is at EXHIBIT FIVE.

[7] *Id. (FN 6 and 7).*

reason for refusing to allow a plaintiff to amend a complaint. (*Id.*).

"[U]nless a substantial reason exists to deny leave to amend, the discretion of the district court is not broad enough to permit denial." *Shipner v. Eastern Airline, Inc.*, 868 F.2d 401, 406 (11th Cir. 1999). Defendant will in no way be prejudiced if changes to the complaint are allowed at this point in the proceedings. Furthermore, there is no apparent reason for denying the motion to amend (if necessary). Consistent with the liberal standard that applies to motions to amend under Rule 15(a)(2), the Court should grant McDaniel's motion to amend, if necessary. By allowing the amendment of the Complaint, this action can more effectively proceeds on its merits.

There will be no undue prejudice if the Court allows McDaniel to amend her complaint. The determination of whether prejudice would occur often includes assessing whether allowing an amendment would result in additional discovery, cost, and preparation to defend against new facts or theories. In this case, Upsher-Smith has not yet answered the complaint nor has discovery begun. If the Complaint is deemed deficient, the Motion for Leave to Amend the Complaint should be granted.

VII. CONCLUSION

The Complaint meets the federal pleading standards and presents plausible claims that move beyond mere speculation and demonstrate entitlement for relief. Allegations include important state law claims that are not pre-empted by the federal regulatory schemes or stare decisis.

McDaniel's claims regarding Upsher-Smith's off-label promotion of amiodarone do not fail for want of causation and their claims regarding the negligent failure to provide mandated warnings do not fail under Tennessee law. Simply stated, amiodarone is never an approved or appropriate treatment for atrial fibrillation. Upsher-Smith promoted it as such and failed to provide the required Medication Guide to Johnny McDaniel, it sold a mislabeled drug in violation of Tennessee law, which resulted in severe injury and death to Johnny McDaniel.

Upsher-Smith's Motion to Dismiss is due to be denied. In the alternative, McDaniel should be allowed to further develop the facts necessary for an additional amendment of the Complaint if the Complaint is not deemed sufficient.

Respectfully Submitted,

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

OF COUNSEL:

E. Kirk Wood
Wood Law Firm, LLC
P. 0. Box 382434
Birmingham, AL 35238-2434
Telephone: 205-612-0243
Facsimile: 866-747-3905
Email: kirk@woodlawfirmllc.com

Dustin Colt Childers
Langston & Lott, P.A.
100 South Main Street
Booneville, MS 38829
Telephone: 662-728-9733
Email: dchilders@langstonlott.com

CERTIFICATE OF SERVICE

This is to certify that on the 21st day of September, 2016, 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:

Eric E. Hudson
Kyle R. Cummins
Butler, Snow, O'Mara, Stevens & Canada, PLLC
6075 Poplar Avenue, Suite 500
Memphis, TN 38119
Telephone: 901-680-7200
Email: eric.hudson@butlersnow.com
Email: kyle.cummins@butlersnow.com

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

U.S. CONST. art. VI

* * *

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.

* * *

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.

(c) Each distributor or packer that receives Medication Guides, or the means to produce Medication Guides, from a manufacturer under paragraph (b) of this section shall provide those Medication Guides, or the means to produce Medication Guides, to each authorized dispenser to whom it ships a container of drug product.

* * *

(e) Each authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent) unless an exemption applies under § 208.26.

* * *