IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PHYLLIS BENNETT, et al., *Plaintiffs*, v. TEVA PHARMACEUTICALS USA, INC. & DOES 1–50, *Defendants*.	:	Civ. No. 19-2126-CFC

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MEMORANDUM OPINION

March 2, 2021
Wilmington, Delaware

CONNOLLY, UNITED STATES DISTRICT JUDGE

Plaintiffs are 129 individuals who allege that they, their spouses, or their related decedents were injured after being prescribed and ingesting amiodarone to treat atrial fibrillation. Plaintiffs have sued Teva Pharmaceuticals USA, Inc., a maker and seller of amiodarone, and 50 unidentified Does. All 129 Plaintiffs allege six causes of action under Delaware law: "Strict Products Liability – Failure to Warn" (Count I); "Negligence – Failure to Warn" (Count II); "Negligence – Marketing and Sale" (Count III); "Negligence *Per Se*" (Count IV); "Strict Liability – Manufacturing Defect" (Count V); and "Fraud and Deceit" (Count VI). D.I. 1 ¶¶ 184-241. Six Plaintiffs also allege a wrongful death claim (Count VII). D.I. 1 ¶¶ 241–247

Pending before me is Teva's motion to dismiss the Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). D.I. 6.

I.

The Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, prohibits a manufacturer from distributing a new drug without first obtaining the approval of the Food and Drug Administration (FDA). 21 U.S.C. § 355(b)(1). The FDA will approve a new (that is, brand-name) drug only if it determines after reviewing the manufacturer's New Drug Application (NDA) that the drug "meets

the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(b) (2020).

Once the FDA has approved a manufacturer's brand-name drug, another company may seek permission to market a generic version of the drug pursuant to what are commonly called the Hatch–Waxman Amendments to the Food, Drug, and Cosmetic Act. Pub. L. No. 98-147, 98 Stat. 1585 (1984). Those amendments allow a generic competitor to file an abbreviated new drug application (ANDA) to obtain FDA approval. The ANDA is called "abbreviated" because the generic drug applicant does not need to show with independent (and costly) evidence such as clinical trial results that its drug is safe and effective. Instead, the generic applicant can piggyback on the safety and efficacy showing made by the brand manufacturer so long as it can demonstrate that its generic drug is the equivalent of the brand-name drug. To gain approval, "[a] generic drug application must also show that the safety and efficacy labeling [it] propose[s] . . . is the same as the labeling approved for the brand-name drug." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612–13 (2011) (internal quotation marks, and brackets omitted) (citing 21 U.S.C. § 355(j)(2)(A)(v)). Once approval is gained and the generic drug is on the market, the generic manufacturer must maintain the labeling approved by the FDA. *Id.* at 613–21.

The FDA's labeling regulations include a requirement that the manufacturer make available to distributors, packers, and authorized dispensers of the drug "sufficient numbers" of "Medication Guides" to distribute to each patient with each prescription. 21 C.F.R. § 208.24. The content, format, and even the "tone" and font size of a Medication Guide are governed by detailed regulations issued by the FDA. *See* 21 C.F.R. § 208.20. A Medication Guide must contain, among other things, a "nontechnical, understandable" explanation of the approved uses of the drug and its risks and side effects. *Id.*

Teva makes and sells amiodarone, the generic version of Cordarone®, a brand-name drug manufactured by Wyeth Pharmaceuticals, Inc. The FDA approved Cordarone® only for use as a "drug of last resort" by patients suffering from life-threatening ventricular fibrillation and ventricular tachycardia. D.I. 1 ¶¶ 102–103. The FDA did not approve and has never approved the use of Cordarone® for the treatment of atrial fibrillation, a rhythm condition of the atrial chambers of the heart. D.I. 1 ¶ 103.

Although the FDCA generally prohibits manufacturers from marketing a drug for an unapproved or "off-label" use, doctors are free to prescribe a drug for off-label use if they deem it medically appropriate for a patient. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239–40 (3d Cir. 2012). Plaintiffs allege here that they, their spouses, or their related decedents

were injured or died after taking amiodarone prescribed by a doctor for off-label treatment of non-life-threatening atrial fibrillation.

In their brief filed in opposition to Teva's motion, Plaintiffs provide this helpful summary of the sprawling, repetitive, and at times vague allegations set forth in their 313-page Complaint:

> The complaint alleges in detail how [Teva] violated its state-law duty to adequately warn of the true indicated uses and complications associated with Amiodarone by, *inter alia*, failing to provide Medication Guides in proper form to distributors or patients' pharmacies, with the result that Plaintiffs did not receive the FDA-required guides. [Teva] also failed to report all adverse events to the FDA (the only way to warn doctors fully). Finally, Plaintiffs allege that [Teva] misrepresented Amiodarone, either directly or through omission, as safe to prescribe for atrial fibrillation ("a-fib") through [medical reference] apps such as Epocrates and PDR and in other communications.

D.I. 13 at 1.

II.

Teva makes numerous arguments in support of its motion to dismiss and asks in the alternative that I stay the case. I need address only Teva's first argument—that Plaintiffs' strict liability, negligence, and fraud claims are preempted by federal law.

Section 337(a) of the FDCA provides that all "proceedings for the enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Company v. Plaintiffs'*

Legal Committee, 531 U.S. 341, 349 n.4 (2001), the Supreme Court held that this provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA. Accordingly, when a plaintiff's state-law tort claims "exist solely by virtue of the FDCA," the claims are preempted and barred by federal law. *Id.* Such claims include "state-law fraud-on-the FDA claims," as these claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350.

As Plaintiffs acknowledge in their briefing, their strict liability, negligence and fraud claims are based on three theories: (1) Teva failed to make available Medication Guides in proper form to distributors of amiodarone; (2) Teva failed to report to the FDA adverse events associated with the use of amiodarone; and (3) Teva engaged in or benefitted from the misleading off-label promotion of amiodarone for treatment of non-life-threatening atrial fibrillation. D.I. 13 at 1. Plaintiffs acknowledge in the Complaint and their briefing that all three theories are premised on alleged violations of the FDCA or regulations promulgated pursuant to the FDCA. *See* D.I. 1 ¶ 116 (noting that the FDA has mandated pursuant to 21 C.F.R. §§ 208.1(c) and 208.24(c) "that the warnings included in the Medication Guides also go directly to the distributors"); D.I. 1 ¶ 191 (noting that the FDA requires manufacturers to use the Adverse Events Reporting System to

report all serious injuries related to Amiodarone use); D.I. 1 ¶ 105 (noting that "it is unlawful" under 21 U.S.C. §§ 331(d), 352(f), and 355, "for a manufacturer to promote any drug for a use not described in the approve labeling of the drug"); D.I. 13 at 3 (discussing how distribution and content requirements for Medication Guides are established by federal regulations promulgated under the FDCA); D.I. 13 at 10 (noting that federal law required Teva to report adverse events to the FDA).

Plaintiffs argue, however, that their claims are not barred by *Buckman* because the claims do not exist solely by virtue of the FDCA. According to Plaintiffs, Teva's alleged failures to provide sufficient numbers of Medication Guides in proper form and to report adverse events to the FDA and its complicity in a fraudulent campaign to promote the off-label use of amiodarone to treat atrial fibrillation constitute "breach[es] of pre-existing state duties." D.I. 13 at 5. Plaintiffs say those duties originate in a Delaware statute that prohibits the making and selling of misbranded drugs (16 Del. Code §§ 3302 and 3308(4)) and section 388 of the Restatement (Second) of Torts. D.I. 13 at 5.

The express terms of Delaware's misbranding statute contradict Plaintiffs' assertion that the duties imposed by that statute predate or exist independent of the FDCA. Section 3302 of Title 16 of the Delaware Code prohibits the manufacture or sale of "misbranded" drugs. Section 3308(4) provides that "a drug is deemed to

be misbranded . . . [i]f it is included in the definition of misbranding in the Federal Food, Drug and Cosmetic Act [21 U.S.C. § 301 *et seq.*])." Accordingly, a private cause of action based on section 3302 is prohibited by § 337(a) and preempted under *Buckman*.

Section 388 of the Restatement subjects a supplier of chattel to liability for failure to provide adequate warnings of dangers associated with the chattel's intended uses. D.I. 13 at 5.[1] Delaware's Supreme Court expressly "embrace[d]" section 388 as Delaware law in *Ramsey v. Georgia S. Univ. Advanced Dev. Ctr.*, 189 A.3d 1255, 1273 (Del. 2018). But neither section 388 nor any other Delaware law cited by Plaintiffs refers to, let alone imposes an obligation on drug

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[1] Under section 388, a direct or indirect supplier of chattel is liable for

> physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
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> > (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
> >
> > (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
> > (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Restatement (Second) of Torts § 388 (Am. L. Inst. 1965).

manufacturers to distribute, Medication Guides. On the contrary, the Medication Guide is a creature of the FDA. As the Complaint itself notes, the requirement that drug manufacturers distribute Medication Guides arises from—and only from—21 C.F.R. § 208.24, a regulation promulgated by the FDA pursuant to the FDCA. *See* D.I. 1 ¶ 93.[2] Thus, to the extent Plaintiffs' claims are based on an alleged failure to distribute Medication Guides, the claims are preempted and barred by § 337(a) and *Buckman. McDaniel v. Upsher–Smith Laboratories, Inc.*, 893 F.3d 941, 944 (6th Cir. 2018); *Frei v. Taro Pharmaceuticals U.S.A., Inc.*, 443 F. Supp. 3d 456, 468 (S.D.N.Y. 2020).

Section 388 also says nothing about an obligation to report adverse events to the FDA. Such an obligation, to the extent it exists, would arise from the FDA's own regulations. (Neither party cites a statute or regulation that imposes an obligation to report adverse events, but both parties state that federal law imposes such an obligation on drug manufacturers. D.I. 1 ¶101; D.I. 13 at 10; D.I. 8 at 7–8.) But in any event, a claim based on a failure to report adverse events to the

[2] Plaintiffs allege in paragraph 93 of the Complaint that Teva's legal duties included "ensuring the FDA required[-]Medication Guide meets the requirements set out in 21 C.F.R. §208.20 and ensuring the Medication Guide is distributed to pharmacies and patients in compliance with 21 C.F.R. §208.24." D.I. 1 ¶ 93. To be clear, neither § 208.24 nor any other federal regulation requires drug manufacturers to distribute Medication Guides to patients. As noted above, § 208.24 requires drug manufacturers to distribute Medication Guides to "distributors, packers, and authorized dispensers."

FDA would constitute a fraud-on-the FDA claim that *Buckman* expressly held is preempted by § 337(a). Accordingly, to the extent Plaintiffs' claims are based on alleged failures by Teva to report adverse events to the FDA, the claims are barred by § 337(a) and *Buckman*.

To the extent Plaintiffs' claims are based on the content of the Medication Guides and information about off-label use of amiodarone in the medical reference apps Epocrates and PDR, the claims are preempted under the Supreme Court's decision in *PLIVA, Inc., v. Mensing*, 564 U.S. 604 (2011). As the Court explained in *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), *Mensing* "held that state failure-to-warn claims [against generic manufacturers] were pre-empted by the FDCA because it was impossible for drug manufacturers like [the defendant in *Mensing*] to comply with both the state-law duty to label their products in a way that rendered them reasonably safe and the federal-law duty not to change their drugs' labels." *Id.* at 488 (citing *Mensing*, 564 U.S. at 617–19). Plaintiffs allege in their Complaint that the Medication Guides and the information provided about amiodarone in Epocrates and PDR constitute labeling. *See* D.I. 1 ¶ 116 (alleging that "[f]ailure by [Teva] to provide the Medication Guide and to ensure its distribution in accordance with the requirements applicable to [Teva] results in the distribution of a mislabeled drug[.]"); D.I. 1 ¶ 112 (alleging that "the information about a particular drug in Epocrates or the PDR is also considered 'labeling' under

21 U.S.C. § 321(m) and as such cannot be false or misleading."). Accordingly, Plaintiffs' state-law claims based on Teva's alleged actions and failures with respect to the Medication Guides, Epocrates, and the PDR are preempted under *Mensing*.

In an apparent attempt to escape preemption under *Mensing*, Plaintiffs argue that they "do not seek a label change." D.I. 13 at 5. But this assertion cannot be squared with Plaintiffs' allegation that Teva's failure to report adverse events constituted a failure to warn under section 388 of the Restatement. *See* D.I. 13 at 11. If proven to be true, that allegation necessarily means that the warnings in the Medication Guides, Epocrates, and the PDR—warnings that Plaintiffs themselves define in their Complaint as constituting labeling, *see* D.I. 1 ¶¶ 112, 116—were inadequate because they did not reflect adverse events. If a claim depends on an allegation of inadequate labelling, it does seek a label change and it is preempted under *Mensing*.

Finally, Plaintiffs argue that in *Wyeth v. Levine*, 555 U.S. 555 (2009) the Supreme Court "held that *Buckman* preemption would not preclude state-law, failure-to-warn claims like the claims at issue here." D.I. 13 at 7. *Wyeth*, however, was decided before *Mensing* and it involved a *brand* manufacturer, not a generic manufacturer. As the Court explained in *Mensing*, the "federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully

different than those that apply to generic drug manufacturers." 564 U.S. at 625. The Court in *Wyeth* held that a state tort-law failure-to-warn claim against a brand-name manufacturer is not preempted because it is possible for a brand manufacturer to comply with both federal and state law since FDA regulations allow brand manufacturers to strengthen unilaterally the warnings on their labels without prior FDA approval. 555 U.S. at 572–73; *see also Mensing*, 564 U.S. at 624–25 (discussing *Wyeth*). Generic manufactures, however, are prohibited by federal law from changing their labels to meet state-law warning requirements. *Mensing*, 564 U.S. at 614–19. For that reason, state-law failure-to-warn claims based on inadequate labeling are preempted against generic manufacturers, as it would be "impossible for [them] to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same." *Id.* at 618.

III.

Because Counts I through VI are preempted, I will grant Teva's motion to dismiss them. It is undisputed that the wrongful death claim alleged in Count VII is a "derivative claim" premised entirely on Counts I through VI. D.I. 13 at 20 n.7. Accordingly, I will also dismiss it. *Deuley v. DynCorp Int'l, Inc.*, 8 A.3d 1156, 1165 (Del. 2010) (dismissing derivative wrongful death claim where underlying claims failed).

Plaintiffs asked in their answering brief for leave to amend in the event I "conclude[d] that any of [their] allegations are insufficiently pleaded." D.I. 13 at 20. Having concluded that the claims fail as a matter of law because they are preempted by federal law, I find that leave to amend would be futile and therefore will dismiss the Complaint with prejudice.

The Court will issue an Order consistent with this Memorandum Opinion.

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ORDER

At Wilmington this Second day of March in 2021, IT IS HEREBY ORDERED, for the reasons stated in the accompanying Memorandum Opinion, that:

1. Defendant's Motion to Dismiss (D.I. 6) is GRANTED.
2. The Complaint is DISMISSED WITH PREJDUICE.
3. The Court of the Clerk is directed to CLOSE the case.

UNITED STATES DISTRICT JUDGE