IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

HACAH BOROS, as Administrix of the Estate of JONATHAN BOROS; G.B, an infant under the Age of 14 years, by her guardian HACAH BOROS; N.B, an infant under the age of 14 years, by his Guardian HACAH BOROS; and HACAH BOROS Individually,	)	
v.	)	C.A. No. N15C-04-029 JRJ
PFIZER, INC.; PFIZER INTERNATIONAL LLC; PFIZER PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA INC.; PLIVA, INC. a/k/a SIDMAK LABORATORIES, INC.; and DOES 1 through 10	)	
Defendants.	)	

Date Submitted: February 25, 2016
Date Decided: May 25, 2016

Upon Defendant Teva Pharmaceuticals USA Inc.'s Motion for Judgment on the Pleadings: **DENIED.**

James D. Heisman, Esquire, and Diane M. Coffey, Esquire, Bern Ripka LLP, Wilmington, DE, Hunter Shkolnik, Esquire (argued) (*pro hac vice*), and Staesha Rath, Esquire (*pro hac vice*), Napoli Shkolnik PLLC, New York City, NY. Attorneys for Plaintiffs.

William R. Denny, Esquire, and Michael B. Rush, Esquire, Potter Anderson & Corroon LLP, Wilmington, DE, Jeffrey Peck, Esquire (argued) (*pro hac vice*), and Jennifer Snyder Heis, Esquire (*pro hac vice*), Ulmer & Berne, LLP, Cincinnati, OH. Attorneys for Defendant Teva Pharmaceuticals USA Inc.

I. INTRODUCTION

On April 2, 2015, Plaintiffs filed a Complaint against Defendants Pfizer Inc., Pfizer Pharmaceuticals, Inc., and Pfizer International LLC (collectively "Pfizer"); Teva Pharmaceuticals USA Inc. ("Teva"); Pliva, Inc. a/k/a Sidmak Laboratories, Inc. ("Pliva"); and DOES 1 through 10 (collectively "Defendants"), alleging that Plaintiff Jonathan Boros ("Decedent") was injured and died as a proximate result of ingesting either the brand-name azithromycin drug Zithromax, manufactured and sold by Pfizer, or the generic equivalent, manufactured and sold by one of the other named Defendants.[1]

Although Plaintiffs assert seven causes of action against Defendants, the core of the claims is the same—Defendants failed to adequately warn Decedent of the safety issues regarding the azithromycin that he ingested.[2]

On May 21, 2015, Pfizer filed a Motion to Dismiss the Complaint[3] and on July 8, 2015, Teva filed a Motion for Judgment on the Pleadings.[4] At oral argument on Pfizer's Motion to Dismiss, Plaintiffs voluntarily dismissed their

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[1] Compl. (Trans. ID. 57018818). Plaintiffs in this case are as follows: Hacah Boros, as Administrix of the Estate of Jonathan Boros; G.B, an infant under the Age of 14 years, by her Guardian Hacah Boros; N.B, an infant under the age of 14 years, by his Guardian Hacah Boros; and Hacah Boros, Individually. *Id.* ¶¶ 1–5.

[2] Plaintiffs allege: (1) Strict Liability; (2) Strict Liability Design Defect; (3) Marketing Defect and Manufacturing Defect; (4) Negligence; (5) Breach of Warranty; (6) Breach of Implied Warranty; and (7) Loss of Consortium.

[3] Trans. ID. 57519127.

[4] Trans. ID. 57523364.

claims against Pfizer (rendering that motion moot) because it is undisputed that Decedent never ingested Pfizer's brand-name Zithromax product.[5]

Before the Court is Defendant Teva's Motion for Judgment on the Pleadings. For the reasons that follow, the Motion is **DENIED.**

II. BACKGROUND

A. Relevant Federal Regulations

The Federal Food, Drug, and Cosmetic Act ("FDCA"), provides the statutory framework for federal regulation of prescription drugs in the United States.[6] Under the FDCA, drug manufacturers must obtain approval from the United States Food and Drug Administration ("FDA") before marketing any drug in interstate commerce.[7] In the case of a brand-name manufacturer seeking to market a new prescription drug, FDA approval can be secured only by submitting a "New Drug Application" ("NDA"), which must include extensive studies of the drug's safety and effectiveness,[8] and the proposed labeling for the drug.[9]

Prior to 1984, both brand-name manufacturers and generic manufacturers were required to file an NDA to receive approval from the FDA to market a drug.[10] In 1984, Congress passed the Drug Price Competition and Patent Term Restoration

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[5] Trans. ID. 58326397.
[6] The FDCA is codified at 21 U.S.C. § 301 *et seq.*
[7] 21 U.S.C. § 355(a).
[8] 21 U.S.C. § 355(a)-(i); *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470–71 (2013).
[9] 21 U.S.C. § 355(b)(1)(F); *Bartlett*, 133 S. Ct. at 2471.
[10] *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011).

Act of 1984, known as the "Hatch–Waxman Act," which, among other things amended the FDCA to reduce the time and cost required to obtain FDA approval for generic drugs.[11]

Under the Hatch–Waxman Act, a generic manufacturer can obtain FDA approval by simply showing that the generic drug is identical to the already-approved brand-name drug.[12] Instead of an NDA, the generic manufacturer must file an "Abbreviated New Drug Application" ("ANDA") demonstrating that the generic product is a "bioequivalent" and chemical equivalent of the brand-name drug.[13] Additionally, the Hatch–Waxman Act requires that the labeling and warnings for the generic drug be identical to the labels for the FDA approved brand-name drug.[14] Thus, brand-name drug manufacturers and generic drug manufacturers have different federal drug labeling duties.[15] A brand-name manufacturer seeking FDA approval for a new drug is responsible for the accuracy

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[11] *Bartlett*, 133 S. Ct. at 2471.
[12] *Id.* at 2470–71.
[13] 21 U.S.C. § 355(j). "Bioequivalent" means that the generic drug must have the same "rate and extent of absorption" as the brand-name drug. 21 U.S.C. § 355(j)(8)(B). Chemically equivalent means that the generic drug must have the same active ingredient or active ingredients, route of administration, dosage form, and strength. *Bartlett*, 133 S. Ct. at 2471 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii)). Thus, generic drug manufacturers have a federal duty of "sameness." *Mensing*, 564 U.S. at 613.
[14] 21 U.S.C. § 355(j)(2)(A)(v); *Bartlett*, 133 S. Ct. at 2471.
[15] *Mensing*, 564 U.S. at 613

and adequacy of its label, and a generic manufacturer must ensure that its label is the same as the brand-name drug's label.[16]

B. Zithromax/Azithromycin

In 1981, Pliva patented the drug azithromycin, a broad-spectrum macrolide antibiotic.[17] In 1986, Pfizer and Pliva entered into a licensing agreement, which gave Pfizer the exclusive rights to manufacture, label, distribute, market, and sell azithromycin in Western Europe and the United States.[18]

The FDA approved azithromycin under the brand-name Zithromax, and in 1991, Pfizer launched Zithromax in the United States.[19] In December 2002, Pfizer's exclusive licensing rights for azithromycin lapsed, and generic manufacturers began producing azithromycin.[20] Defendant Teva manufactures, markets, distributes, and sells azithromycin pursuant to an ANDA.[21] As such, under federal law, Teva's generic azithromycin product must be the bioequivalent and chemical equivalent of the brand-name Zithromax, and the labels must be identical to the Zithromax labels.[22]

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[16] *Id.* (internal citations omitted).
[17] Compl. ¶¶ 19, 21.
[18] *Id.* ¶ 22.
[19] *Id.* ¶¶ 20, 23.
[20] *Id.* ¶ 27.
[21] *Id.* ¶¶ 27–28.
[22] *Id.* ¶ 31.

On March 12, 2013, the FDA issued a new warning regarding potentially fatal irregular heart rhythms that can occur among patients taking Zithromax,[23] and stated that the Zithromax label would be updated with stronger language regarding the risk of life threatening irregular heart rhythms.[24] The FDA warning was prompted by the agency's review of two studies that assessed the potential for Zithromax to cause abnormal changes in the electrical activity of the heart.[25]

C. Decedent's use of azithromycin

Plaintiffs allege that Decedent's pharmacist dispensed to Decedent a generic form of azithromycin allegedly manufactured and sold by one of the Defendants.[26] On April 2, 2013, Decedent ingested the drug as prescribed, and the next day collapsed in front of his wife, Plaintiff Hacah Boros.[27] Decedent's wife called 911 and paramedics transported Decedent to the hospital.[28] Decedent underwent an EKG, which showed a prolonged QT interval, leading to a cardiac arrhythmia.[29]

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[23] *Id.* ¶ 33.
[24] *Id.* ¶¶ 33, 37.
[25] *Id.* ¶ 34. A May 2012 study published in the New England Journal of Medicine reported a higher risk of cardiovascular deaths, and deaths from any cause, in persons treated with a 5-day course of Zithromax compared to those treated with amoxicillin. *Id.* ¶ 35. The FDA also reviewed a study that determined Zithromax can lead to a potentially fatal heart rhythm known as prolonged QT interval, in which the timing of the heart's contractions becomes irregular. *Id.* ¶ 36.
[26] *Id.* ¶¶ 71, 73.
[27] *Id.* ¶¶ 74–75.
[28] *Id.* ¶¶ 76–78.
[29] *Id.* ¶ 78.

After approximately forty minutes of unsuccessful attempts at resuscitation, Decedent was pronounced dead at 11:36 a.m. on April 3, 2013.[30]

III. STANDARD OF REVIEW

Pursuant to Superior Court Civil Rule 12(c), a party may move for judgment on the pleadings after the pleadings are closed but within such time as not to delay the trial. The Court must accept all well pled allegations of fact as true and all reasonable inferences are construed in favor of the non-moving party.[31] A motion for judgment on the pleadings will be granted only when no material issues of fact exist and the movant is entitled to judgment as a matter of law.[32]

IV. DISCUSSION

Teva argues that the claims against Teva are pre-empted by federal law, which precludes a generic drug manufacturer from unilaterally altering a drug's warning labels. The Supremacy Clause of the United States Constitution establishes that the laws and treaties of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the

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[30] *Id.* ¶¶ 79–80.

[31] *Silver Lake Office Plaza, LLC v. Lanard & Axilbund, Inc.*, 2014 WL 595378, at *6 (Del. Super. Jan. 17, 2014); *Doe v. Bradley*, 2011 WL 290829, at *3 (Del. Super. Jan. 21, 2011)

[32] *Artisans' Bank v. Seaford IR, LLC*, 2010 WL 2501471, at *1 (Del. Super. June 21, 2010) (citing *Gonzales v. Apartment Cmtys. Corp.*, 2006 WL 2905724, at *1 (Del. Super. Oct. 4, 2006)); *Bradley*, 2011 WL 290829, at *3 ("Indeed, when considering a motion under Rule 12(c), the Court must decline to construe facts not clearly alleged in the complaint or to decide disputed issues of fact, but rather must confine its review to deciding issues of law as framed by the well pled allegations in the complaint.").

Contrary notwithstanding."[33] If a state law "directly conflicts" with a federal law, "state law must give way."[34] Even in the absence of an express pre-emption provision, a state law may be pre-empted "where it is impossible for a private party to comply with both state and federal requirements."[35] "[I]mpossibility pre-emption is a demanding defense."[36]

In support of its pre-emption argument, Teva relies on two decisions from the United States Supreme Court involving generic pharmaceutical products. In *PLIVA, Inc. v. Mensing*, the plaintiffs brought actions against a generic drug manufacturer alleging that the generic manufacturer knew or should have known that the long-term use of its generic drug metoclopramide carried a high risk of a severe neurological disorder and that the drug's labels did not adequately warn of that risk.[37] Under the state law applicable to the actions in *Mensing*, all drug manufacturers had a duty to adequately warn consumers and safely label their products.[38] It was undisputed in *Mensing* that state law required the generic drug manufacturer to use a "different, safer" label than the brand-name manufacturer's

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[33] U.S. Const. art. VI, cl. 2.
[34] *Mensing*, 564 U.S. at 617.
[35] *Id.* at 618 (internal quotations omitted); *Bartlett*, 133 S. Ct. at 2473.
[36] *Wyeth v. Levine*, 555 U.S. 555, 573 (2009); *Deweese v. Nat'l R.R. Passenger Corp. (Amtrak)*, 590 F.3d 239, 246 (3d Cir. 2009) (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)).
[37] *Mensing*, 564 U.S. at 611.
[38] *Id.*

label.[39] The U.S. Supreme Court explained that federal regulations require that the labels on generic drugs match the label on the corresponding brand-name drug, thus preventing generic drug manufacturers from independently changing their drug's safety labels.[40] The *Mensing* Court held that the state law failure-to-warn claims were pre-empted by the FDCA because it was impossible for the generic drug manufacturer to comply with both the state law duty to label its products in a way that rendered them reasonably safe and the federal law duty not to change the generic drug's safety labels from the brand-name drug.

In *Mutual Pharmaceuticals, Inc. v. Bartlett*, the issue was whether a state law design-defect claim against a generic drug manufacturer was pre-empted by federal law.[41] The plaintiff in *Bartlett* developed an acute case of toxic epidermal necrolysis and suffered severe physical disabilities after taking a generic form of an anti-inflammatory pain reliever. The plaintiff brought failure-to-warn and design-defect claims against the generic drug manufacturer under state law, which required drug manufacturers to ensure that the products they designed, manufactured, and sold were not unreasonably unsafe, either because of inadequate warnings or inadequate design.[42] At the time the plaintiffs ingested the generic drug, the FDA and brand-name manufacturer had not changed the warning labels

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[39] *Id.* at 611–12.
[40] *Id.* at 612–13.
[41] 133 S. Ct. 2466 (2013)
[42] *Id.* at 2470.

to more explicitly warn against toxic epidermal necrolysis.[43] Consequently, the state law imposed a duty on the generic manufacturer to change the labeling to provide stronger warnings.[44] The *Bartlett* Court found that it was impossible for the generic manufacturer to simultaneously comply with the state law duty to strengthen the warnings and the federal law duty prohibiting generic drug manufacturers from making any unilateral change to the drug's labels.[45]

Contrary to Teva's argument that Plaintiffs' claims are pre-empted by federal law under the controlling precedents of *Mensing* and *Bartlett*, *Mensing* and *Bartlett* do not provide generic drug manufacturers with blanket immunity against state law warning claims. For example, the *Mensing* Court noted that "federal law would permit the [generic drug] [m]anufacturers to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so."[46] The crux of the U.S. Supreme Court's decisions in *Mensing* and *Bartlett* was that the plaintiffs claimed state law required generic drug manufacturers to provide stronger warnings than the brand-name drug. Thus, under *Mensing* and *Bartlett*, impossibility pre-emption applies to claims involving a generic drug manufacturer's failure to unilaterally alter its labeling to comply with state law warning duties.

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[43] *Id.* at 2472.
[44] *Id.* at 2470.
[45] *Id.* at 2474–79.
[46] *Mensing*, 564 U.S. at 620.

In contrast to the claims alleged in *Mensing* and *Bartlett*, however, the Plaintiffs in this case do *not* allege that state law required Teva to vary its labeling from the brand-name drug. Rather, Plaintiffs allege that Teva should have updated its warning labels to match the brand-name Zithromax labels, and the labels on Teva's azithromycin (that Decedent ingested) failed to adequately warn about the risk of irregular heart rhythms.[47] Accordingly, Teva is not entitled to judgment on the pleadings based on impossibility pre-emption because it was possible for Teva to fulfill both its duty under federal law to update its labels and its duty under state law to adequately warn consumers.[48]

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[47] *See Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1061 (D. Or. 2013) ("Unlike the failure to warn claim in *Mensing*, plaintiffs do not claim that Pliva was required to use a different or stronger warning label; they merely claim that, under Oregon law, Pliva was negligent by failing to update its label to match the name-brand label—a requirement that is consistent with the FDCA. Thus, because plaintiffs' state-law claim does not make it impossible for Pliva to comply with federal law, no conflict exists and preemption is not warranted."); *Cooper v. Wyeth, Inc.*, 2012 WL 733846, at *4 (M.D. La. Mar. 6, 2012) ("Since, as *Mensing* makes clear, the FDA's labeling regulations set the ceiling for labeling strength, any state law purporting to impose more stringent requirements would be preempted. However, a generic drug manufacturer's failure to adhere to the brand-name label the generic drug is tied to would plainly violate federal law and likely violate state law . . . . In the latter scenario, the requirements of state law would coextend with, but would not exceed, the requirements of federal law, rendering impossibility preemption inapplicable."); *Johnson v. Teva Pharm. USA, Inc.*, 2012 WL 1866839, at *3 (W.D. La. May 21, 2012), *aff'd,* 758 F.3d 605 (5th Cir. 2014) ("[I]mpossibility preemption would not apply to any requirement . . . that the Generic Defendants update their product labels to reflect labeling changes made by the brand name manufacturer."); *Teva Pharm. USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150, 158 (2013) ("In this case, as in *Fulgenzi v. PLIVA, Inc.*, it was possible for the Teva Defendants to comply with both a federal duty to make their labels match the Fosamax label, and a state tort law duty to prevent harm to the consumers of alendronate sodium. Therefore, the impossibility preemption doctrine does not bar [the] claims.").

[48] *Mensing*, 564 U.S. at 620 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it.").

Teva also argues that Plaintiffs' claims are merely an attempt to enforce the FDCA's "sameness" duty, which requires that the generic drug's labels be identical to the brand-name drug's labels. Pursuant to 21 U.S.C. § 337(a), only the federal government may bring an action to enforce the provisions of the FDCA. Contrary to Teva's arguments, Plaintiffs do not allege a private federal cause of action under the FDCA based on a failure to have the same labels as Zithromax. Rather, Plaintiffs allege that the azithromycin labels did not adequately warn about the risks associated with the drug.[49]

Finally, Teva argues it is entitled to judgment on the pleadings because the Complaint fails to allege any facts based on a "failure to update" theory. Although bare-boned, the Complaint alleges: (1) the FDA stated the Zithromax label would be updated with stronger language regarding the risk of life threatening irregular heart rhythms; (2) Teva should have revised their package inserts following modifications initiated by Pfizer; (3) the warning about the risk of irregular heart rhythms was not included on the label of the generic azithromycin allegedly manufactured by Teva that Decedent ingested; and (4) Decedent died after experiencing a prolonged QT interval, leading to an arrhythmia, the exact cardiac risk that should have been included on the label.

[49] *See e.g.*, Compl. ¶¶ 33–42.

The standard for granting a motion for judgment on the pleadings is strict, and to prevail, the moving party must show that there are no issues of material fact in existence.[50] Teva has failed to meet this burden because genuine issues of material fact exist, including when Pfizer updated the Zithromax label, and what warnings, if any, Teva provided at the time Decedent ingested azithromycin

V. CONCLUSION

For foregoing reasons, Defendant Teva Pharmaceuticals USA Inc.'s Motion for Judgment on the Pleadings is **DENIED.**

IT IS SO ORDERED.

Jan R. Jurden, President Judge

[50] *Artisans' Bank*, 2010 WL 2501471, at *1.