IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

DANIEL CAMEJO,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**C.A. No. N19C-09-023 PRW**
	)	
	)	
ANGELINI PHARMA INC., AND TEVA PHARMACEUTICALS USA, INC.	)	
	)	
	)	
Defendants	)	

Submitted: October 26, 2020
Decided: January 15, 2021

Upon Defendant Angelini Pharma Inc.'s Motion to Dismiss,
GRANTED.
Upon Defendant Teva Pharmaceuticals USA, Inc.'s Motion to Dismiss
GRANTED.

MEMORANDUM OPINION AND ORDER

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WALLACE, J.

Plaintiff Daniel Camejo was prescribed Trazodone, a generic-drug manufactured and sold by Defendant Teva Pharmaceuticals USA, Inc. Trazadone is the generic equivalent of Desyrel, a brand-name drug previously manufactured and sold by Defendant Angelini Pharmaceuticals, Inc. This suit arises as a result of Camejo's ingestion of Trazadone and subsequent development of priapism, a listed side-effect of Trazadone and Desyrel. Before the Court are Teva's and Angelini's (collectively referred to as "Manufacturers") Motions to Dismiss Camejo's Complaint under Superior Court Civil Rule 12(b)(6). For the reasons set forth below, Angelini's and Teva's Motions are **GRANTED** on all counts.

I. FACTUAL AND PROCEDURAL BACKGROUND

In June of 2017, Daniel Camejo suffered insomnia and was prescribed Trazodone by his physician in Los Angeles, California.[1] Trazadone has been approved to treat depression and is commonly used to treat insomnia as well.[2] On November 10, 2017, Camejo took 50mg of Trazodone, as his doctor had prescribed.[3] That night he developed a prolonged and persisting penile erection, known as priapism, a known side-effect of the drug.[4] Camejo, having no knowledge of the

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1 Compl. ¶ 3, Sept. 5, 2019 (D.I. 1).

2 *Id.* ¶ 1.

3 *Id.* ¶ 4.

4 *Id.*

risk of priapism caused by Trazadone, failed to seek medical attention for over 24 hours.[5] Due to this delay, Camejo became impotent at the age of 50.[6]

A. TRAZADONE'S AND DESYREL'S LABELS

Trazadone is a generic medication manufactured and sold by Teva, a Pennsylvania-based Delaware corporation.[7] Desyrel is the brand-name equivalent of Trazadone, manufactured and sold by Angelini, a Maryland-based Delaware corporation.[8] Camejo alleges he suffered his injuries as a result of ingesting Trazadone that was manufactured by Teva.[9] In 2012, Trazadone's label prominently stated, in capital letters, a warning for the risk of priapism:

> TRAZADONE HAS BEEN ASSOCIATED WITH THE OCCURENCE OF PRIAPISM. IN MANY OF THE CASES REPORTED, SURGICAL INTERVENTION WAS REQUIRED AND, IN SOME OF THESE CASES, PERMANENT IMPAIRMENT OF ERECTILE FUNCTION OR IMPOTENCE RESULTED. MALE PATIENTS WITH PROLONGED OR INAPPROPRIATE ERECTIONS SHOULD IMMEDIATELY DISCONTINUE THE DRUG AND CONSULT THEIR PHYSICIAN.[10]

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5 *Id.* ¶ 6.

6 *Id.* ¶ 7.

7 *Id.* ¶ 13.

8 *Id.* ¶ 8.

9 *Id.* ¶ 4.

10 Angelini's Mot. To Dismiss, Ex. E (2012 Trazodone Label), Dec. 12, 2019 (D.I. 28).

The warning on Trazadone's label was identical to Desyrel's label from 2009 to 2012.[11] In 2012, Teva diminished the warning for priapism by altering the verbiage above from Trazadone's label.[12] Teva altered the warning by changing the language, removing the capitalized lettering, and moving it from its prominent position:

> Rare cases of priapism (painful erections greater than 6 hours in duration) were reported in men receiving trazodone. Priapism, if not treated promptly, can result in irreversible damage to the erectile tissue. Men who have an erection lasting greater than 6 hours, whether painful or not, should immediately discontinue the drug and seek emergency medical attention.[13]

The warning for priapism was, in appearance, now indistinguishable from other warnings on Trazadone's label.[14] As a generic-drug manufacturer, Teva had an obligation to conform its label to the label used by the brand-name manufacturer, Angelini.[15] Angelini owned the Desyrel New Drug Application ("NDA") and trademark from 2011 to 2015.[16] Although Teva altered its label between 2012 to

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[11] *Id.*, Exs. C (2009 Desyrel Label), D (2013 Desyrel Label).

[12] *Id.*, Ex. F (2013 Trazodone Label).

[13] *Id.*; *see also* Compl. ¶ 29.

[14] *Id.*, Ex. F.

[15] Compl. ¶ 31.

[16] *Id.* ¶ 9.

2013, this was not prompted by a change in Angelini's label.[17] Indeed, after Teva revised its label, Trazadone's and Desyrel's respective labels were notably different from each other. Camejo aims his allegations of inadequate warning at the revised label Teva started using in 2013.[18] Camejo concedes that Angelini's label was sufficient and that label is not the basis of his complaint.[19]

B. CAMEJO SUES ANGELINI AND TEVA BASED ON THESE LABELS

Camejo brings suit against Angelini and Teva alleging that the supposed insufficient warning on the Trazadone label caused his injuries.[20] Camejo brings four claims against Defendant Angelini including: (1) Strict Liability; (2) Negligence; (3) Breach of Express Warranty; and (4) Innovator Liability.[21] Camejo also brings four claims against Defendant Teva including: (1) Strict Liability – Failure to Adequately Warn; (2) Negligence; (3) Breach of Implied Warranty; and (4) Breach of Express Warranty.[22] Camejo alleges further that additional warnings

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[17] Angelini's Mot. To Dismiss, Exs. C-F; Compl. ¶ 28.

[18] Compl. ¶ 28.

[19] *Id.* ¶ 26.

[20] *Id.* ¶ 51.

[21] *Id.* ¶¶ 52-86.

[22] *Id.*

should have been circulated in letters to various practitioners.[23] And, based on the nature of the injuries and their supposed causation, Camejo suggests that the Court should examine his claims under California law.[24]

Defendants Teva and Angelini now move to dismiss all Camejo's claims via Superior Court Civil Rule 12(b)(6).

II. STANDARD OF REVIEW

A motion to dismiss under Civil Rule 12(b)(6) will be granted where the plaintiff cannot recover "under any reasonably conceivable set of circumstances susceptible of proof."[25] In considering a motion to dismiss, the Court will:

> (1) accept all well pleaded factual allegations as true, (2) accept even vague allegations as "well pleaded" if they give the opposing party notice of the claim, (3) draw all reasonable inferences in favor of the non-moving party, and (4) [not dismiss the claims] unless the plaintiff would not be entitled to recover under any reasonably conceivable set of circumstances.[26]

Yet, "[w]here allegations are merely conclusory . . . (*i.e.*, without specific allegations of fact to support them) they may be deemed insufficient to withstand a

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[23] *Id.* ¶ 48.

[24] *Id.* ¶ 18.

[25] *Begum v. Singh*, 2013 WL 5274408, at *3 (Del. Super. Ct. Sept. 18, 2013).

[26] *See Cent. Mortg. Co. v. Morgan Stanley Mortg. Capital Holdings LLC*, 27 A.3d 531, 535 (Del. 2011) (stating standard for motions to dismiss).

motion to dismiss."[27] The Court "is not required to accept every strained interpretation of the allegations proposed by the plaintiff."[28]

In deciding this Rule 12(b)(6) dismissal motion, the universe of facts that the Court will consider would usually be confined to the Camejo's complaint.[29] But the Court may consider certain extrinsic documents when they are: (1) "integral to [the] plaintiff's claim and incorporated into the complaint (2) . . . not being relied upon to prove the truth of its contents, and (3) . . . an adjudicative fact to judicial notice."[30] Because they fall under one or more of these exceptions, the Court will consider certain attachments to Angelini's motion as part of the universe of facts.[31]

Those attachments include copies of the labels for Trazadone and Desyrel that were being used by Teva and Angelini, respectively, for a range of years.[32] They provide a reliable timeline of when changes in Desyrel's label were (or were not)

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[27] *Lord v. Souder*, 748 A.2d 393, 398 (Del. 2000) (citing *In re Tri-Star Pictures, Inc. Litig.*, 634 A.2d 319, 326 (Del. 1993)).

[28] *Malpiede v. Towson*, 780 A.2d 1075, 1083 (Del. 2001).

[29] *Doe 30's Mother v. Bradley*, 58 A.3d 429, 443 (Del. Super. Ct. 2012).

[30] *In re Gardner Denver, Inc.*, 2014 WL 715705, at *2 (Del. Ch. Feb. 21, 2014).

[31] *Machala v. Boehringer Ingeheim Pharm., Inc.*, 2017 WL 2814728, at *7 & n. 69 (Del. Super. Ct. June 29, 2017) (taking judicial notice of publicly available FDA labels when deciding a motion to dismiss).

[32] Angelini's Mot. To Dismiss, Exs. C-F.

made.[33] These materials are made publicly available by the Food and Drug Administration ("FDA") and within the proper universe of facts to be considered under the specifics of this motion to dismiss.[34]

III. DISCUSSION

Angelini and Teva both move to dismiss all counts of Camejo's complaint for failure to state any claim upon which relief can be granted. Angelini argues that Camejo's concession to consuming Trazadone, and not Desyrel, is dispositive of the strict liability and breach of express warranty claims against it. Additionally, Angelini argues that the alleged claims of innovator liability and negligence are not appropriate under these facts. Teva's motion rests on federal preemption and deference to the FDA.

A. ANGELINI'S MOTION TO DISMISS

1. Delaware's Choice of Law Principles Favor California

Camejo and Angelini dispute which state's law governs Camejo's claims. Delaware courts apply a two-part test in determining the choice of law for products liability actions.[35] First, the Court must determine whether there is an actual conflict

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[33] *Id.*, Ex. B.

[34] *Machala*, 2017 WL 2814728, at *7 & n. 69 (taking judicial notice of publicly available FDA labels when deciding a motion to dismiss does not covert to a motion for summary judgement).

[35] *See Bell Helicopter Textron, Inc. v. Arteaga*, 113 A.3d 1045, 1050 (Del. 2015).

between the laws of the respective sovereigns requested by each party.[36] After showing of an existing conflict, the appropriate choice of law is determined based on the "most significant relationship to the occurrence and the parties."[37]

The conflict between the proposed jurisdictions, Maryland and California, is most relevant to Count V of Camejo's complaint, the innovator liability claim brought against Angelini. Innovator liability allows a plaintiff to circumvent federal preemption of suit against a generic-drug manufacturer by bringing suit against the drug's brand-name manufacturer.[38] Plaintiffs generally argue that because the brand-name manufacturer was in control of the label it should be liable, regardless of whether the plaintiff ingested the brand-name drug.[39] Many courts, including those applying Maryland law, have rejected this theory of liability.[40] These courts

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[36] *Id.*

[37] *Id.*

[38] 4 JAMES T. O'REILLY & KATHERINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION *Preemption and Innovator Liability* § 26:79, Westlaw (database updated November 2020) (citing California, among other, state court cases).

[39] *Id.*

[40] *See In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation*, 756 F. 3d 917 (6th Cir. 2014) (listing state-by-state analyses of claims against brand-name manufacturers); *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994) (holding thatconsumers of a generic equivalent could not recover against the manufacturer of the brand-name under Maryland law); *Grinage v. Mylan Pharmaceuticals*, 840 F. Supp. 2d 862 (D. Md. 2011) (applying Maryland law) *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d. 654 (D. Md. 2010) (holding that drug defect claims must be alleged at the manufacturer of the allegedly defective drug); *Jensen v. American Motors Corp. Inc.*, 427 A.2d 242, 247 (Md. Ct. Spec. App. 1981) ("the plaintiff in product litigation must satisfy three basics . . . 2) the attribution of the defect to the seller").

have chosen not to deviate from the traditional concept of products liability—that a brand-name manufacturer should not face liability for the subsequent effects of a product that it did not manufacture.[41] Unlike the jurisdictions rejectinginnovator liability, California allows consumers of a generic-drug to recover against a brand-name manufacturer based on innovator liability.[42] So with respect to Camejo's allegation of innovator liability against Angelini, a direct conflict exists between Maryland and California.

After a conflict is established, the Court must determine which jurisdiction is most appropriate based on the "most significant relationship to the occurrence and to the parties."[43] This determination requires the consideration of many factors: "(1) the place where the injury occurred; (2) the place where the conduct causing the injury occurred; (3) the domicil, residence, nationality, place of incorporation and

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[41] *See e.g., Foster*, 29 F.3d at 168; *see* Kenneth Sills, Annotation, *Liability of Name Brand Drug Manufacturer for Injury or Death Resulting from Use of Prescription Drug's Generic Equivalent*, 56 A.L.R. Fed 6th 161 (2020) (listing cases which have rejected this theory).

[42] *T.H. v. Novartis Pharmaceuticals Corp.*, 407 P.3d 18, 46 (Cal. 2017) (holding that a brand-name manufacturer's failure to update a warning label was foreseeable); CHILTON DAVIS VARNER & STEPHEN B. DEVEREAUX, BUSINESS AND COMMERCIAL LITIGATION IN FEDERAL COURTS, *No liability for branded drug makers when plaintiff has taken a generic version of the drug* § 112:10 (2020), Westlaw (database updated December 2020).

[43] *Bell Helicopter Textron, Inc.*, 113 A.3d at 1050.

place of business of the parties; and (4) the place where the relationship, if any, between the parties is centered."[44]

The outcome of the first factor in this analysis will generally create a rebuttable presumption in personal injury litigation, unless the place of injury is considered fortuitous.[45] Angelini argues that the place of injury, in this case, is fortuitous and therefore should carry little weight here.

The Delaware Supreme Court's decision in *Ison v. E.I. DuPont de Nemours and Co., Inc.* is helpful in understanding fortuitousness here. In *Ison*, the Court found that the location of an airplane crash was fortuitous because the victims had no other connections to the place of the crash.[46] Using *Ison*, it could be said that in a case like this, the determination for fortuitousness is from the plaintiff's perspective. And from that perspective, California as the place of injury is hardly an isolated or arbitrary location here. Camejo is a resident of California, he was prescribed the medication in California, and his injury subsequently occurred in California.

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[44] *Id.* (quoting Restatement (Second) of Conflicts of Laws § 145(2) (1971)).

[45] *Id.* at 1053; *Ison v. E.I. DuPont de Nemours and Co., Inc.*, 729 A.2d 832, 844 (Del. 1999) (finding place of injury was fortuitous).

[46] *Ison*, 729 A.2d at 844.

The first factor—place of injury—therefore leans convincingly toward California. So when engaging the remainder of the choice of law analysis, the Court must presume that California is the proper choice of law to apply to Camejo's claims. And the remaining factors do little to overcome this presumption.

Although the location of the offending conduct—screening and approving the drug warnings—that allegedly caused the injury and the domiciles of the respective Manufacturers *might* direct the Court elsewhere, Camejo is a resident of California.[47] Manufacturers do business domestically and internationally; under the specifics of this case the locations of their corporate headquarters are of little moment. Lastly, the fourth factor—the place where the relationship between the parties is centered—weighs in favor of California being the appropriate governing jurisdiction. There is no indication that Camejo had any interaction with Manufacturers before he was prescribed and took Trazadone in California.

Accordingly, the Court should analyze Camejo's claims under California law.

2. Count I – Strict Liability

Count I of Camejo's complaint alleges strict liability for a failure to warn of the risks of priapism.[48] "A bedrock principle in strict liability law requires that the

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[47] *Bell Helicopter*, 113 A.3d at 1055; *See Laugelle v. Bell Helicopter Textron, Inc.*, 2013 WL 5460164, at *4 (Del. Super. Ct. Oct. 1, 2013) (giving heightened consideration to the third factor based on the domicile of the survivor plaintiffs).

[48] Compl. ¶¶ 52-56.

'plaintiff's injury must have been caused by a 'defect' in the defendant's product.'"[49] Camejo has conceded that he consumed Trazadone, which is manufactured and sold by Teva, and not Desyrel, which was previously manufactured and sold by Angelini.[50] California does not impose strict liability for a failure to warn against a manufacturer who did not manufacture the defective product that purportedly caused plaintiff's injury.[51] And so, in California a generic-drug consumer cannot bring a strict liability claim suit against a brand-name manufacturer.[52] Because Camejo admits his injuries are due to his ingestion of Trazadone, and not Desyrel,[53] his strict liability claim against Angelini must be dismissed.

3. Count II and V– Negligence and Innovator Liability

Camejo raises claims of negligence and innovator liability against Angelini, arguing that Angelini should have foreseen Camejo's injury due to the inadequate

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[49] *O'Neil v. Crane*, 266 P. 3d 987, 994-95 (Cal. 2012) (citing *Daly v. General Motors Corp.*, 575 P.2d 1162 (Cal. 1978)).

[50] Compl. ¶ 1 (Camejo concedes he ingested Trazadone, and not Desyrel); Mot. to Dismiss Hr'g Tr., at 36, Oct. 26, 2020 (D.I. 54) (Camejo concedes that Angelini was not marketing the drug anywhere in the United States at the time of injury).

[51] *Anderson v. Owens-Corning Fiberglass Corp.*, 53 Cal. 3d 987, 1003-04 (Cal. 1991); *Nelson v. Superior Court*, 50 Cal. Rptr. 3d 684, 687 (Cal. Ct. App. 2006) (outlining the elements of a strict liability claim).

[52] *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 309-10 (Cal. Ct. App. 2008).

[53] Compl. ¶¶ 1, 3, 38.

warning on Teva's label.[54] Innovator liability,as recognized by California law,navigates around the just-mentioned obstacle to a strict liability claim. It affords a generic-drug consumer a path to a brand-name manufacturer's possible liability.[55] And as the paving for Camejo's separately pled negligence and innovator liability claims is the same, the Court maps its analysis for both here. [56]

As a matter of law, Angelini had a duty to use ordinary care in its conduct.[57] The general rule in California is that all persons have a duty to use ordinary care to prevent others from being injured as a result of their conduct.[58] A satisfactory showing of innovator liability or negligence requires Camejo to prove that Angelini, while placing a pharmaceutical drug in the stream of commerce with the requisite warnings, did not do so with reasonable care which was a subsequent cause of his injuries.[59] California courts have addressed just such liability.

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[54] *Id.* ¶¶ 57-61, 71-86.

[55] *See T.H. v. Novartis Pharmaceuticals Corp.*, 407 P.3d 18, 47 (Cal. 2017).

[56] *Id.*; *Conte*, 85 Cal. Rptr. 3d at. at 310.

[57] CAL. CIV. CODE § 1714 (West 2020); *T.H. v. Novartis*, 407 P.3d at 29-36 (declining to carve an exception to the statutory duty); *Conte*, 85 Cal. Rptr. 3d at 311.

[58] CAL. CIV. CODE § 1714 (West 2020).

[59] *McIntyre v. The Colonies-Pacific, LLC.*, 175 Cal. Rptr. 3d 440, 444 (Cal. Ct. App. 2014) (outlining the prima facie elements for negligence).

In *T.H. v. Novartis*, the plaintiffs' mother took terbutaline, a generic version of the brand-name drug Brethine, until the 32nd week of her pregnancy to suppress premature labor.[60] By the time the plaintiff fraternal twins turned three years old, a pediatrician diagnosed them both with developmental delays; by the time they were five, the twins were diagnosed with autism.[61] Plaintiffs brought suit against Defendant Novartis, Brethine's manufacturer, for a failure to warn of certain fetal brain development risks.[62] Novartis said it breached no recognizable duty (*i.e.* it could not be found to have caused injury) to plaintiffs' mother because their mother took the generic-drug, and not the brand-name version it had previously manufactured and sold.[63] But the California court held that regardless of which variation of the drug plaintiff's mother ingested, dismissal was not warranted if there was sufficient proof pled to support the contention that Novartis' own brand-name's label was inadequate.[64] Of particular importance to the California courts was the

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60 *T.H. v. Novartis*, 407 P.3d at 22.

61 *Id.* at 22-23.

62 *Id.* at 22.

63 *Id.*

64 *Id.* at 43, 48-49.

fact that the generic-drug's "label allegedly was the same as that prepared by Novartis."[65] This is not so here.

Camejo concedes that Angelini's label of Desyrel was sufficient and all his objections are reserved for Teva's Trazadone label.[66] Camejo's complaint alleges that Teva's warning for the risk of priapism was diminished because it was removed from its prior prominent position, now drawn in lowercase, and had altered verbiage.[67] These allegations are in reference to Teva's label after its revisions between 2012 and 2013. But as Camejo admits, there is neither evidence nor credible suggestion that Angelini's label ever changed from 2009 to 2013.[68] Indeed the record demonstrates that the Angelini and Teva labels were far different from each other, unlike the two labels in *T.H. v. Novartis*.[69]

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[65] *T.H. v. Novartis Pharmaceuticals Corp.*, 199 Cal. Rptr. 3d 768, 779 (Cal. Ct. App. 2016) ("If Novartis knew or should have known about fetal risk associated with tocolytic use and failed to disclose the risk while it owned the NDA, Novartis's moral culpability is not lessened simply because it no longer owned the NDA when the minors were allegedly harmed by their mother's ingestion of the harmed by their mother's ingestion of the generic form of the medication, particularly since the label allegedly was the same as that prepared by Novartis.").

[66] Compl. ¶ 26.

[67] *Id.* ¶ 29.

[68] Mot. to Dismiss Hr'g Tr., at 24 (requesting for motion to be converted to summary judgement so discovery is permitted).

[69] Angelini's Mot. to Dismiss Exs. C-F.

Brand-name manufacturers and generic-drug manufacturers do have a "duty of sameness."[70] Pursuant to this duty, applicants for generic-drug approval must show that active ingredients, dosage form, pharmacological class *and the label*, among other aspects, mirror the brand-name bioequivalent.[71] The generic-drug manufacturer (here, Teva) must conform its labels to those of the bioequivalent brand-name manufacturer (here, Angelini).[72] Camejo has not expressly pled that Teva, as a generic-drug manufacturer, changed its label in response to Angelini changing its label. And, when pressed at argument, Camejo has posited that because Teva was bound to a duty of sameness, Angelini *must* have changed its label and subsequently prompted Teva to change its label as well.[73]

The changes-being-effected ("CBE") process allows manufacturers to make necessary changes to labels with the FDA.[74] It "allow[s] changes to generic-drug labels only when a generic-drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions."[75] Camejo provides no

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[70] *Pliva, Inc. v. Mensing*, 564 U.S. 604, 616 (2011).

[71] 21 U.S.C.A. § 355(j)(2)(A) (West 2018).

[72] *Pliva, Inc.*, 564 U.S. at 613.

[73] Mot. to Dismiss Hr'g Tr., at 28.

[74] *Pliva, Inc.*, 564 U.S. at 614.

[75] *Id.*

support, factual or other, to support his blithe assertion that Teva's label change must have come from Angelini. And he gives no credence whatsoever to the far more likely event—that Teva changed its Trazadone label at the FDA's behest. Yet, the record fully supports Angelini's assertion that the labels for Trazadone and Desyrel were completely different in 2012 and 2013, with the Desyrel label retaining the prominent priapism warning. So, unlike the defendant in *T.H. v. Novartis*, because Trazadone's and Desyrel's labels were notably different, Angelini's conduct could not have caused Camejo's injury.

While the standard of review under a 12(b)(6) motion requires the Court to draw all reasonable inferences in favor of the non-moving party, the Court must "ignore conclusory allegations that lack specific supporting factual allegations."[76] Even when drawing all rational inferences in Camejo's favor, there is simply no reasonably conceivable set of circumstances here that would support a finding of innovator liability and negligence and allow for recovery from Angelini under California law.

4. Count IV – Breach of Express Warranty

Breach of express warranty claims are between a product's seller and the

[76] *Athene Life and Annuity Co. v. Am. Gen. Life Ins. Co.*, 2020 WL 2521557, at *8 (Del. Super. Ct. May 18, 2020); *see also Przywara v. State Pers. Comm'n*, 1988 WL 97847, at *1 (Del. Super. Ct. Sept. 14, 1988) ("This Court will not be forced to speculate as to matters not in the record.").

product's buyer.[77] A satisfactory showing of breach of express warranty requires the plaintiff to prove that "(1) the seller's statements constitute an affirmation of fact or promise or a description of the goods; (2) the statement was part of the basis of the bargain; and (3) the warranty was breached."[78] Additionally, the buyer must have relied on an affirmation of fact by the seller.[79]

Camejo has already conceded that he consumed Trazadone, manufactured and sold by Teva, not Desyrel.[80] Camejo in no way relied on any supposed deficiency in Angelini's Desyrel label.[81] In fact, Camejo says that Angelini's label was sufficient and his complaint is directed toward revisions made by Teva between 2012 to 2013.[82] Consequently, Angelini's role as neither a buyer nor a seller and Camejo's admitted lack of reliance is fatal to his claim for breach of express warranty against Angelini.

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[77] CAL. COM. CODE § 2313 (West 2020).

[78] *Weinstat v. Dentsply Internat., Inc.*, 103 Cal. Rptr. 3d 614, 626 (Cal. Ct. App. 2010)

[79] *Burr v. Sherwin Williams Co.*, 268 P.2d 1041, 1049 (Cal. 1954); *Seely v. White Motor Co.*, 403 P.2d 145, 148 (Cal. 1965); *but see Weinstat*, 103 Cal. Rptr. 3d at 625 ("breach of express warranty arises in the context of contract formation in which reliance plays no role.").

[80] Compl. ¶ 1.

[81] *Id*. ¶30.

[82] *Id*. ¶¶ 26-28.

B. TEVA'S MOTION TO DISMISS

1. Camejo's State-Law Claims Fall to Federal Preemption

Teva moves to dismiss all claims against it by relying on the United States Supreme Court's decision in *Pliva, Inc. v. Mensing*, arguing that state law claims based on inadequate warning are preempted by federal law.[83] In *Pliva*, the Supreme Court reconciles state and federal law regarding the approval process for generic-drugs and delineates the expectations for generic-drug manufacturers.[84] The Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Amendments, regulates the generic-drug approval process.[85] These amendments allow generic-drug manufacturers to submit an abbreviated NDA (ANDA), which requires a showing that the generic-drug is a biosimilar to an approved brand-name drug.[86]

Before the approval of the Hatch-Waxman Amendments, the FDA approval process for all drugs required costly and lengthy clinical testing.[87] Passage of these amendments now allows generic-drug manufacturers to develop generic-drugs at far

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[83] *Pliva Inc.*, 564 U.S. at 618.

[84] *Id.*

[85] *Id.* at 607.

[86] *Id.* at 613.

[87] *Id.* at 612.

less expense and "without duplicating the clinical trials already performed on the equivalent brand-name drug."[88] But the price of such changes was the imposition of a "duty of sameness." The duty of sameness requires that to obtain generic-drug approval an applicant must show that the generic's active ingredients, dosage form, pharmacological class *and the label*, among other aspects, mirror the brand-name bioequivalent.[89] The CBE process only allows a generic-drug's label to be changed as a result of (1) a change in the respective biosimilar brand-name's label, or (2) "to follow the FDA's instructions."[90] Due to these restrictions, a generic-drug manufacturer cannot "unilaterally . . . strengthen a generic drug's warning label" without violating federal statutes that require a generic-drug's label to conform to the biosimilar brand-name's label.[91]

With the backdrop of this regulatory framework, the Supreme Court in *Pliva* held that a state-law duty, alleged by plaintiffs, of placing a different, stronger, label on the generic-drug, was impossible to reconcile with federal law.[92] "If the Manufacturers had independently changed their labels to satisfy their state-law duty,

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88 *Id.*

89 *Id.* at 615; 21 U.S.C.A. § 355(j)(2)(A) (West 2018).

90 21 C.F.R. § 314.94(a)(8)(iv); *Pliva, Inc.*, 564 U.S. at 614.

91 *Pliva, Inc.*, 564 U.S. at 614.

92 *Id.* at 618.

they would have violated federal law." [93] Federal and state courts, including those in California, have consistently followed *Pliva*'s guidance in this area.[94]

Here, Camejo's claims of (1) Strict Liability (2) Negligence (3) Breach of Implied Warranty, and (4) Breach of Express Warranty, against Teva are all grounded in a purported inadequate warning.[95] And here Teva has raised the affirmative defense of federal preemption under *Pliva* and applicable federal regulations. According to the FDA's interpretation of the CBE process, the change in Teva's Trazadone label would be prompted either by a change in Angelini's label or at the behest of the FDA. As noted before, Angelini didn't change its label. And Camejo has not alleged Trazadone's labeling change was done by Teva without directive by and approval from the FDA. Like the manufacturers in *Pliva*, as a generic-drug manufacturer, Teva could not have unilaterally changed its label without violating federal law. And as our highest court found in *Pliva* federal law controls preempts a state-law claim like Camejo's.

Even if Camejo could bring a California-law claim for inadequate warning

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93 *Id.*

94 *See e.g., Patton v. Forest Labs., Inc.*, 2018 WL 5269239, at *10 (C.D. Cal. Sept. 19, 2018); *Ko v. Mutual Pharm. Co. Inc.*, 2013 WL 5692375 (N.D. Cal. Oct. 18, 2013); *but see Teva Pharmaceuticals USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150, 158 (Cal. Ct. App. 2013) (federal preemption does not bar suit against a generic-brand-name manufacturer who failed to conform to a change in the brand-name manufacturer's label).

95 Compl. ¶¶ 55 60, 65, 68.

against Teva, the priapism warning Teva had on its Trazadone label is such that under no reasonably conceivable set of circumstances could liability be found and recovery from Teva occur.[96]

In *Brown v. Superior Court*, the California Supreme Court held that a "manufacturer cannot be held strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities . . ."[97] Following *Brown*, the California Court of Appeals explained the limited state-law liability of a manufacturer who includes a specific warning: "a patient's expectations regarding the effects of such a drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties."[98]

The warning in Teva's revised label, even if considered "diminished" from years prior, still patently warns of priapism as a potential Trazadone side effect. It states the risk of priapism in detail, explaining the condition and potential consequences. And the warning label plainly explains the urgency of seeking medical attention for "[m]en who have an erection lasting greater than 6 hours." In

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[96] *See Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988); *Trejo v. Johnson & Johnson*, 220 Cal. Rptr. 3d 127, 156 (Cal Ct. App. 2017).

[97] *Brown*, 751 P.2d at 483.

[98] *Trejo*, 220 Cal. Rptr. 3d at 156.

short, given the undisputed content in the Trazadone labeling that clearly relayed the priapism risk, Camejo's "diminished warning" claim provides no reasonably conceivable basis for a finding of liability against Teva under California law.[99]

2. The is No Affirmative Duty to Send 'Dear Doctor' Letters

In the face of Teva's demonstration of federal preemption, Camejo's last and remaining theory asks this Court to be the first in the country to impose an affirmative duty on generic-drug manufacturers to send "Dear Doctor" letters—those are separate letters to medical practitioners that reiterate certain warnings in the FDA-approved drug. The Court declines this invitation.

"Dear Doctor" (more officially referred to as Dear Healthcare Provider) letters were originally developed as a means for manufacturers to relay key information to healthcare professionals about a drug.[100] These letters are intended to relay "important information" to physicians including information that is a "(1) significant

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[99] *Id.*; *see Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001) (Under California law, "[a] plaintiff asserting causes of action based on a failure to warn must prove not only that no warning was provided or the warning was inadequate . . ."); *see also Anderson*, 810 P.3d at 558 ("Negligence law in a failure-to-warn case requires a plaintiff prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care . . ."); *Carlin v. Superior Court*, 920 P.2d 1347, 1355 (Cal. 1996) ("We emphasize, however that the 'consumer expectation' aspect of a breach of warranty action is subject, in the prescription drug context, to the general rule, discussed above, that warnings concerning the drug's properties are properly directed to the *physician* rather than the patient.").

[100] James W. Huston et al., *Dear Doctor Letters: Lessons in Statutory Interpretation, Preemption, Proximate Causation, and Subsequent-Remedial Measures*, 22 ANNALS OF HEALTH LAW 445 (2013).

hazard to health (2) important changes in drug package labeling, and (3) a correction of prescription drug advertising or labeling."[101]

In *Pliva*, the Supreme Court limits the ability of a generic-drug manufacturer to send a "Dear Doctor" letter.[102] First, the language of a "Dear Doctor" letter must be "the same in language and emphasis as labeling approved or permitted" by the FDA.[103] Additionally, in adherence to the "duty of sameness," a generic-drug manufacturer can only send a "Dear Doctor" letter if prompted by the brand-name counterpart.[104] Citing another United States Supreme Court case, in *Sorrell v. IMS Health Inc.*,[105] Camejo argues that the High Court did not intend to federally preempt the ability of a generic-drug manufacturer to send a "Dear Doctor" letter and that Teva should be held liable for not having done so here.

Camejo's attempt to devise a California state-law claim for failure to warn derived from his suggested duty to send a "Dear Doctor" letter highlighting the priapism warning fails both on the law and on logic.

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[101] *Id.* at 447 (citing 21 C.F.R. § 200.5).

[102] *Pliva, Inc.*, 564 U.S. at 615-16.

[103] *Id.* at 615; 21 C.F.R. § 201.100(d)(1).

[104] *Pliva, Inc.*, 564 U.S. at 615; *In re Darvocet*, 756 F.3d at 933-34 (6th Cir. 2014); *Boros v. Pfizer, Inc.*, 2019 WL 1558576, at *6 (Del. Super. Ct. Mar. 25, 2019).

[105] *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 564 (2011) (holding that a law which disfavors pharmaceutical manufacturers in the marketing space violated the First Amendment).

First, Camejo's reliance on *Sorrell* is misplaced; that case pertained to pharmaceutical marketing rather than pharmaceutical labeling.[106] And *Sorrell* spoke to pharmaceutical companies' permitted speech for marketing, it certainly neither invited nor demanded their speech in labeling.

Second, even if Camejo's claim were not preempted by the truly applicable federal law, as pled, it lacks logical coherence. Camejo's chief complaint against Teva is that its diminished priapism warning was inadequate. Yet, Camejo admits that under extant federal law and regulation any "Dear Doctor" letter would have to contain that same precise warning without further adornment or elaboration. Undeterred, Camejo posits that creating a ubiquitous state-law duty[107] for a drug company to pick out one of the myriad side-effect warnings (whether inadequately penned or not) from its product's packaging, draft and distribute a single side-effect-targeted letter to health care providers with just that exact warning language (again, whether inadequately penned or not) that holds the company liable for inadequate warning if it does not makes sense. It doesn't.

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[106] *Willis v. Abbott Labs*, 2017 WL 5988215, at *5 (W.D. Ky. Dec. 1, 2017) (restricting *Sorrell* as pertaining to marketing and not labeling).

[107] And recall, Camejo asks to the Court to declare this newborn duty not as a matter of Delaware state tort law, but for California. On that, the Court, cannot deliver. *See Perlman v. Vox Media, Inc.*, 2020 WL 3474143, at *9 n.98 (Del. Super. Ct. Jun. 24, 2020) (noting the caution with which a Court proceeds in declaring novel law for other states: "engaging *dicta* to explore [a] rule's boundaries . . . in Delaware would, at very best, be unwise—unnecessarily declaring those boundaries for our cross-continent sister in the present case would, at very least, be foolish").

The Court must reject Camejo's exhortation to declare that Teva had an affirmative duty to send a "Dear Doctor" letter containing that same allegedly deficient warning he complains of elsewhere in his case.

IV. CONCLUSION

There is no doubt Daniel Camejo suffered a serious medical event and must now live with the permanent result thereof. From his complaint one could draw the reasonable inference that Teva's Trazadone—even though taken as prescribed—may have set off that serious medical event. Priapism is a rare but known and warned-of side effect with that particular prescription medication. But through his complaint, Camejo fails to bring even a single claim upon which relief from either Angelini or Teva can be granted. Even drawing all inferences Camejo's favor, there is simply no reasonably conceivable set of circumstances susceptible of proof that would allow recovery against either Angelini or Teva. And so, both companies' motions to dismiss must be **GRANTED** on all counts.

IT IS SO ORDERED.

Paul R. Wallace

Paul R. Wallace, Judge