2020 PA Super 278

JANNINE ZITNEY AND STEVE ZITNEY	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellants	:	
	:	
	:	
v.	:	
	:	
	:	
WYETH LLC., WYETH	:	No. 3369 EDA 2019
PHARMACEUTICALS, INC.MORTON	:	
GROVE PHARMACEUTICALS, INC.,	:	
TEVA PHARMACEUTICALS USA, INC.,	:	
A.K.A IVAX PHARMACEUTICALS,	:	
PLIVA, INC., BARR	:	
PHARMACEUTICALS, LLC., A.K.A	:	
BARR PHARMACEUTICALS, INC FK.,	:	
BARR LABORATORIES, INC.,	:	
DURAMED PHARMACEUTICALS, INC.,	:	
QUALITEST PHARMACEUTICALS,	:	
INC., VINTAGE PHARMACEUTICALS,	:	
LLC., GENERICS BIDO I., LLC,	:	
INDIVIDUAL, A.K.A QUALIITEST	:	
PHARMACEUTICALS., HARVARD	:	
DRUG GROUP, LLC, A.K.A MAJOR	:	
PHARMACEUTICALS, INC.,	:	
PHARMACEUTICAL ASSOCIATES,	:	
INC., BEACH PRODUCTS, INC.,	:	
UNITED RESEACH LABORATORIES,	:	
INC., MUTUAL PHARMACEUTICAL	:	
COMPANY, INC., SILARX	:	
PHARMACEUTICALS, INC., SANDOZ,	:	
INC., ANIP ACQUISITION COMPANY,	:	
A.K.A A&I PHARMACEUTICALS, A.K.A	:	
ANI PHARMACEUTICALS, A.K.A ANIP	:	
PHARMACEUTICALS, WATSON	:	
LABORATORIES, INC., ACTAVIS	:	
ELIZABETH LLC, INDIVIDUAL, A.K.A	:	
PUREPAC PHARMACEUTICALS DBA.,	:	
APP PHARMACEUTICALS LLC., A.K.A	:	
ABRAXIS PHARMACEUTICALS DBA.,	:	
AMNEAL PHARMACEUTICALS, LLC.,	:	
BEDFORD LABORATORIES, HOSPIRA	:	
INC., MCKESSON CORPORATION,	:	

INDIVIDUALLY, A.K.A NORTHSTAR :
RX, LLC DBA., NORTHSTAR RX LLC, :
RUGBY LABORATORIES, INC., :
NORBROOK INC. USA, SMITH & :
NEPHEW, INC., VISTAPHARM, INC., :
ROXANE LABORATORIES, INC., :
INDIV THE CORPORATION TRUST :
COMPANY, USL PHARMA, INC., PAR :
PHARMACEUTICAL INC., HALSEY :
DRUG, LLC INDIVIDUALLY, A.K.A :
HALSEY DRUG CO INC, DBA., :
SUPERPHARM, INC., PACO :
PHARMACEUTICAL SERVICES, INC., :
SCHERING CORPORATION, IVAX :
PHARMACEUTICALS, INC., GOLDLINE :
LABORATORIES INC., INDIVI, A.K.A :
IVAX PHARMACEUTICALS DBA., :
BRISTOL MYERS SQUIBB CO., A.K.A :
APOTHECON INC DBA., APOTHECON, :
INC., PFIZER, INC., INVAMED, INC., :
KING PHARMACEUTICALS, INC., :
A.K.A A.L. PHARMA INC FKA., A.K.A :
ALPHARMA INC DBA., A.K.A :
ALPHARMA-BARRE NATIONAL., :
RICHMOND PHARMACEUTICALS, :
INC., KAREN TOBIN, M.D., SCHWARZ :
PHARMA, INC., ALAVEN :
PHARMACEUTICAL LLC., BAXTER :
HEALTHCARE CORPORATION., AND :
WOCKHARDT USA. :

Appeal from the Order Entered October 16, 2019
In the Court of Common Pleas of Philadelphia County Civil Division at
No(s): No. 110204100

BEFORE: LAZARUS, J., DUBOW, J., and FORD ELLIOTT, P.J.E.

OPINION BY DUBOW, J.: **FILED DECEMBER 1, 2020**

Jannine Zitney ("Mrs. Zitney") and Steve Zitney ("Mr. Zitney") (collectively, "Appellants"), appeal from the October 16, 2019 Orders entered in the Philadelphia County Court of Common Pleas granting summary

judgment in favor of Appellees, PLIVA, Inc. ("PLIVA") and Teva Pharmaceuticals USA, Inc. ("Teva") (collectively, "Appellees"). After careful review, we affirm.

Background

Wyeth, LLC ("Wyeth") manufactures the drug Reglan. Teva and PLIVA[1] manufacture Reglan's generic equivalent, metoclopramide. In the 1980s, the Food and Drug Administration ("FDA") approved Reglan and metoclopramide for the treatment of chronic digestive disorders. Physicians also used metoclopramide "off-label"[2] to treat nausea associated with a range of illnesses, including migraines. Since the 1980s, Reglan's label contained a warning that its use was associated with an increased risk of tardive dyskinesia.[3]

In July 2004, Wyeth updated the Reglan label to include language indicating that metoclopramide should not be used for longer than 12 weeks. In June 2005, Teva sought FDA approval to update its metoclopramide label to mirror the Reglan label. On January 17, 2017, the FDA approved Teva's label update.[4]

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[1] PLIVA is a wholly-owned subsidiary of Teva.

[2] The term "off-label" refers to the use of a FDA-approved drug for an unapproved use.

[3] Tardive dyskinesia is a neurological disorder characterized by involuntary movements of the face and jaw.

[4] The record is unclear as to when PLIVA updated its label to conform to the July 2004 Reglan label.

In early 2010, the Philadelphia County Court of Common Pleas formed the Reglan/metoclopramide mass tort litigation. ***See In Re Reglan®/metoclopramide Litigation***, January Term 2010 No. 1997, Case Management Order 1, docketed on February 16, 2010. Pursuant to Case Management Order 1, a Master Long-Form Complaint was filed asserting allegations common to all plaintiffs in the litigation. ***See*** Case Management Order 1 at § III(A). Thereafter, the trial court required each individual plaintiff to file only a case-specific short-form Complaint, which incorporated by reference the Master Long-Form Complaint and set forth the factual circumstances unique to that individual plaintiff. ***See id.*** at § III(C).

The Instant Litigation

Mrs. Zitney has suffered from debilitating migraine headaches for more than forty years. Between 2004 and 2009, Dr. Karen Tobin, Mrs. Zitney's neurologist, prescribed metoclopramide to treat the nausea associated with Mrs. Zitney's migraines. Dr. Tobin instructed Mrs. Zitney to take metoclopramide on an as-needed basis. Mrs. Zitney's pharmacist dispensed metoclopramide manufactured by PLIVA on four occasions from October 31, 2004, to December 4, 2006. The pharmacist also dispensed metoclopramide manufactured by Teva on four occasions between December 28, 2007, and November 21, 2008.

In December 2009, Mrs. Zitney complained of an eye twitch to Dr. Tobin. Additionally, on multiple occasions starting in 2009, Mrs. Zitney complained of muscle spasms in her back and neck. Dr. Vernon Neppe, a

neuropsychiatrist, opined that Appellant suffers from tardive dyskinesia caused by her metoclopramide use.[5]

On February 28, 2011, Appellants commenced this action by filing a 14-count short-form Complaint against 50 defendants. Appellant's claims included: (1) strict liability failure to warn; (2) strict liability design defect; (3) negligence; (4) negligence *per se*; (5) fraud and intentional misrepresentation; (6) constructive fraud; (7) breach of implied warranty; (8) unfair trade practices; (9) unjust enrichment; (10) negligent misrepresentation; (11) civil conspiracy; (12) loss of consortium; (13) gross negligence/malice; and (14) punitive damages. ***See*** Complaint, 2/28/11. By January 2019, all defendants other than PLIVA and Teva had settled with Appellants or had been dismissed from the case.

On April 3, 2019, the trial court granted partial summary judgment in favor of Teva on the basis of federal preemption as to Appellants' claims for: (1) strict liability failure to warn; (2) strict liability design defect; (3) fraud and intentional misrepresentation; (4) constructive fraud; (5) breach of implied warranty; (6) unfair trade practices, and (7) negligent misrepresentation.[6]

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[5] Dr. Neppe examined and observed Mrs. Zitney, reviewed the video of her deposition to observe her symptoms over a period of hours, and reviewed her medical and pharmacy records. He opined to a reasonable medical probability that Mrs. Zitney's metoclopramide exposure caused her movement disorder. ***See*** Motion for Summary Judgment, 4/25/19, at 4.

[6] PLIVA did not seek summary judgment on the basis of federal preemption.

On April 25, 2019, Appellants filed a Motion for Partial Summary Judgment asserting that they were entitled to judgment as a matter of law against Teva on Appellants' failure to warn claim. In particular, Appellants argued that Teva was negligent because it failed to inform Dr. Tobin about the July 2004 updates to the Reglan label and the corresponding updates to its metoclopramide label through a "Dear Health Care Provider" ("DHCP") letter. ***See*** Motion for Summary Judgment, 4/25/19, at 7; Letter Brief, 7/10/19, at ¶ 13. Stated differently, Appellants based their failure to warn claim on the manner in which Appellees notified Dr. Tobin of the warnings, not on the warnings themselves.

On June 3, 2019, PLIVA filed a Motion for Summary Judgment in which it argued that it was entitled to judgment as a matter of law on all of Appellants' claims. Two days later, on June 5, 2019, Teva filed a similar Motion for Summary Judgment.

On July 10, 2019, Appellants filed a "Reply Brief in Support of [Appellants'] Motion for Summary Judgment; Response Brief to Defendant's Motion for Summary Judgment on Preemption, State Duty to Warn and Causation; and [Appellants'] Response to Defendant's Motion to Strike Testimony of Vernon Neppe, M.D., Ph.D." Reply Brief, 7/10/19. On July 25, 2019, Appellees' filed a Reply in support of their Motions for Summary Judgment.

After considering the Motions filed by the parties, the trial court concluded that Pennsylvania law does not impose a duty on drug

manufacturers to convey safety warnings in any manner other than by including them in a product's package insert shipped with the product. Consequently, it found that because PLIVA and Teva had undisputedly complied with that mandate, they had not breached their duty to warn Appellant by not providing Dr. Tobin with a DHCP letter. Therefore, on October 16, 2019, the trial court entered Orders granting PLIVA's and Teva's Motions for Summary Judgment and dismissing Appellants' claims against them with prejudice.

This timely appeal followed. Both Appellants and the trial court have complied with Pa.R.A.P. 1925.

Appellants raise the following issue on appeal:

> [D]oes a prescription drug manufacturer's duty to provide product warnings extend to doctors who foreseeably rely on a manufacturer's product information when prescribing a medication, even if the prescription was filled with the generic version of the prescribed?

Appellants' Brief at 4.

Appellants challenge the trial court's Orders granting summary judgment in favor of PLIVA and Teva. Our Supreme Court has clarified our role as the appellate court as follows:

> On appellate review, then, an appellate court may reverse a grant of summary judgment if there has been an error of law or an abuse of discretion. But the issue as to whether there are no genuine issues as to any material fact presents a question of law, and therefore, on that question our standard of review is *de novo*. This means we need not defer to the determinations made by the lower tribunals. To the extent that this Court must resolve a

> question of law, we shall review the grant of summary judgment in the context of the entire record.

Summers v. Certainteed Corp., 997 A.2d 1152, 1159 (Pa. 2010) (citations and quotation omitted).

A trial court may grant summary judgment "only in those cases where the record clearly demonstrates that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." ***Id.*** (citation and quotation omitted); ***see also*** Pa.R.C.P. No. 1035.2(1). "When considering a motion for summary judgment, the trial court must take all facts of record and reasonable inferences therefrom in a light most favorable to the non-moving party." ***Summers***, ***supra*** at 1159 (citation omitted). "In so doing, the trial court must resolve all doubts as to the existence of a genuine issue of material fact against the moving party, and, thus, may only grant summary judgment where the right to such judgment is clear and free from all doubt." ***Id.*** (citation and internal quotation marks omitted).

The party moving for summary judgment bears the burden of showing that no genuine issue of material doubt exists and that it is entitled to judgment as a matter of law. ***Ford v. American States Ins. Co.***, 154 A.3d 237, 244 (Pa. 2017).

Appellants claim the trial court erred in finding that Appellees had not breached their duty to warn Appellants of the dangers of metoclopramide. Appellant's Brief at 13-15. Appellants assert that Appellees' conduct fell short of Pennsylvania law requiring drug manufacturers to provide warnings and related prescribing information to physicians because Appellees did not convey

the required safety information directly to Dr. Tobin through a DHCP Letter. ***Id.*** Appellants further argue that the trial court erred in concluding that, by updating their drug labels, Appellees' had adequately warned Dr. Tobin of the dangers posed by metoclopramide. ***Id.*** at 15-18. Last, Appellants aver that entry of summary judgment was inappropriate because whether PLIVA and Teva breached their duty to notify Dr. Tobin of metoclopramide's known risks is a question of fact for the jury and not a question of law for the court to decide. ***Id.*** at 24-26.

"[W]here the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, *i.e.*, the manufacturer's negligence, is the only recognized basis of liability." ***Hahn v. Richter***, 673 A.2d 888, 891 (Pa. 1996).

With respect to negligence, a plaintiff in a products liability case must show that: (1) the product was defective; (2) the defect caused the plaintiff's injury; and (3) the defect existed at the time the product left the manufacturer. ***Demmler v. SmithKline Beecham Corp.***, 671 A.2d 1151, 1153-54 (Pa. Super. 1996). "A product may be deemed defective if it lacks adequate warnings or instructions necessary for safe use of the product." ***Id.*** at 1154 (citation omitted). However, a pharmaceutical product, when "accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." ***Id.*** (citing Restatement (Second) of Torts, § 402A, Comment k).

"Pennsylvania applies the learned intermediary doctrine to claims for failure to warn involving pharmaceutical drugs." ***Simon v. Wyeth Pharmaceuticals, Inc.***, 989 A.2d 356, 368 (Pa. Super. 2009). Under the learned intermediary doctrine, drug manufacturers must direct required drug-safety warnings to physicians, and not to patients. ***Id.*** ***See also Dion v. Graduate Hosp. of Univ. of. Penna.*** 520 A.2d 876, 879 (Pa. Super. 1987) (noting that "where the drug is available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor.") "Thus, in an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate." ***Daniel v. Wyeth Pharmaceuticals, Inc.***, 15 A.3d 909, 924 (Pa. Super. 2011) (citations and quotation omitted).

As noted above, Appellants do not dispute that the contents of the Reglan and metoclopramide labels were adequate to satisfy Appellees' duty to warn. Instead, citing the learned intermediary doctrine's requirement that pharmaceutical companies direct drug warnings to physicians and not to the general public, Appellants challenge the trial court's conclusion that by merely including warning labels containing warnings about metoclopramide's safety in the drugs' packaging, Appellees had satisfied their legal duty to warn. In support of this claim, Appellants baldly assert, without citation to any authority, that the learned intermediary doctrine imposes upon Appellees a

duty to warn Dr. Tobin individually through a DHCP letter of the risks posed by Mrs. Zitney's use of metoclopramide.

In explaining its conclusion that Appellees were entitled to judgment as a matter of law, the trial court noted as follows:

> Here, [Appellants] do not argue Teva or PLIVA distributed their metoclopramide without the FDA approved label. Similarly, [Appellants] conceded the contents of [Appellees'] warnings was proper and adequate. Accordingly, since Teva and PLIVA distributed their metoclopramide with labels containing warnings that [Appellants] concede are sufficient, [Appellees] have fulfilled their duty to warn under Pennsylvania law.

Trial Ct. Op. at 10.

We agree with the trial court. Moreover, and contrary to Appellants' claim, Pennsylvania law does not impose on drug manufacturers a duty to send DHCP letters to prescribing physicians like Dr. Tobin. Because Pennsylvania law does not impose upon Appellees the heightened duty advocated by Appellants, and because Appellants conceded that Appellees fulfilled their duty to provide content-appropriate warning labels in their metoclopramide packaging, the trial court properly found that Appellees had not breached their duty to Appellants. Accordingly, Appellees were entitled to judgment as a matter of law and the trial court, therefore, did not err in entering summary judgment in favor of Appellees.[7]

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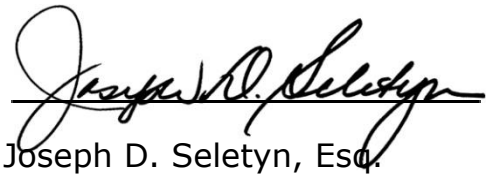
[7] With respect to Appellants' contention that whether PLIVA and Teva breached their duty to notify Dr. Tobin of metoclopramide's known risks is a question of fact for the jury and not a question of law for the court to decide, this Court's review of the record indicates that Appellants failed to preserve

Orders affirmed.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 12/01/2020

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this issue before the trial court and, instead, raised this issue for the first time on appeal. ***See*** Pa.R.A.P. 302 ("Issues not raised in the lower court are waived and cannot be raised for the first time on appeal.") They have, therefore, waived this claim. Moreover, it is axiomatic that whether the law imposes a duty on a defendant is a question of law. ***See Truax v. Roulhac***, 126 A.3d. 991, 1000 (Pa. Super. 2015) ("While the existence of a duty is a question of law, whether there has been a neglect of such duty is generally for the jury."). Thus, even if Appellants had not waived this claim, it would fail.