SILVA V. SMITHKLINE BEECHAM CORP.

ANTHONY AND CHENG SILVA,
Individually and as Personal Representatives
of THE ESTATE OF SUSAN SILVA,
DECEASED; and ANTHONY SILVA JR.,
and JINLEN SILVA, AS SURVIVING SIBLINGS
OF SUSAN SILVA,
Plaintiffs-Appellants,
v.
SMITHKLINE BEECHAM
CORPORATION, d/b/a
GLAXOSMITHKLINE,
Defendant-Appellee,
and
LOVELACE HEALTH SYSTEM,
INC.; and DR. ISABEL LOPEZ-COLBERG,
Defendants.

No. 31,276

COURT OF APPEALS OF NEW MEXICO

February 7, 2013

APPEAL FROM THE DISTRICT COURT OF VALENCIA COUNTY, William A. Sanchez, District Judge

COUNSEL

Bowles & Crow, Jason Bowles, B.J. Crow, Monnica L. Garcia, Albuquerque, NM, for Appellants

Modrall, Sperling, Roehl, Harris, & Sisk, P.A., Alex C. Walker, Albuquerque, NM, King & Spalding, LLP, Stephen B. Devereaux, Robert B. Friedman, Heather M. Howard, Atlanta, GA, Domenici Law Firm, P.A., Peter V. Domenici, Jr., Charles N. Lakins, L. Hollingsworth, Albuquerque, NM, for Appellees

JUDGES

TIMOTHY L. GARCIA, Judge. WE CONCUR: CYNTHIA A. FRY, Judge, LINDA M. VANZI, Judge

AUTHOR: TIMOTHY L. GARCIA

MEMORANDUM OPINION

GARCIA, Judge.

After a user of a generic prescription medication known as paroxetine committed suicide, her relatives brought a wrongful death products liability action against the manufacturer of the name-brand form of paroxetine that is registered with the Food and Drug Administration (FDA) as Paxil. The district court granted summary judgment in favor of the manufacturer of Paxil, and the patient's relatives filed this appeal. We affirm.

BACKGROUND

Paxil and its generic equivalent (Generic Paroxetine) are selective serotonin reuptake inhibitors designed to treat depression and anxiety. Smithkline Beecham Corporation, d/b/a, Glaxosmithkline (GSK) manufactures Paxil and Paxil CR. Teva Pharmaceuticals, USA (Teva) manufactures Generic Paroxetine.

On May 13, 2004, Dr. Isabel Lopez-Colberg prescribed Paxil or Generic Paroxetine to Susan Silva (Patient). On April 13, 2006, Patient committed suicide. Throughout the course of her treatment, Patient's prescription was filled with both Paxil and Generic Paroxetine. At the time of her death, however, Patient's prescription had been filled solely with Teva's Generic Paroxetine for more than a year.

Following Patient's death, Patient's relatives (Plaintiffs) filed a product liability suit for wrongful death alleging, among other things, that GSK provided inadequate warnings about the risks of Paxil and Generic Paroxetine. GSK moved for summary judgment on Plaintiffs' claims, arguing that Patient was not exposed to Paxil at the time of her death. The district court granted GSK's motion for summary judgment, determined that GSK could not be held liable for injuries related to Patient's consumption of Generic Paroxetine, and dismissed all claims against GSK. Plaintiffs timely appealed the district court's grant of summary judgment in favor of GSK.

STANDARD OF REVIEW

We review de novo a district court's grant of summary judgment, construing the evidence most favorably to the non-moving party. *City of Albuquerque v. BPLW Architects & Eng'rs, Inc.*, 2009-NMCA-081, ¶ 7, 146 N.M. 717, 213 P.3d 1146; *Headley v. Morgan Mgmt. Corp.*, 2005-NMCA-045, ¶ 5, 137 N.M. 339, 110 P.3d 1076. "Summary judgment is appropriate where there are no genuine issues of material fact and the

movant is entitled to judgment as a matter of law." *Self v. United Parcel Serv., Inc.*, 1998-NMSC-046, ¶ 6, 126 N.M. 396, 970 P.2d 582. "If the facts are undisputed and only a legal interpretation of the facts remains, summary judgment is the appropriate remedy." *Bd. of Cnty. Comm'rs v. Risk Mgmt. Div.*, 120 N.M. 178, 179, 899 P.2d 1132, 1133 (1995). "Summary judgment should not be granted when material issues of fact remain or when the facts are insufficiently developed for determination of the central issues involved." *Vieira v. Estate of Cantu*, 1997-NMCA-042, ¶ 17, 123 N.M. 342, 940 P.2d 190. We conclude that there are no material facts in dispute and we can decide this case as a matter of law.

"A defendant seeking summary judgment . . . bears the initial burden of negating at least one of the essential elements upon which the plaintiff's claims are grounded." *S. Farm Bureau Cas. Co. v. Hiner*, 2005-NMCA-104, ¶ 9, 138 N.M. 154, 117 P.3d 960 (internal quotation marks and citation omitted). "Once such a showing is made, the burden shifts to the plaintiff to come forward with admissible evidence to establish each required element of the claim." *Id.*

DISCUSSION

Plaintiffs claim that even though Patient was taking Generic Paroxetine—a drug not manufactured by GSK—for the fifteen months prior to her death, GSK could nevertheless be deemed liable for her death because Patient became addicted to GSK's Paxil CR when she took it from September 2004 to December 2004. As a result, Plaintiffs claim that there are issues of fact as to whether Patient's exposure to Paxil CR contributed to her death.

Plaintiffs failed to meet their burden to defeat summary judgment on the basis of this argument. GSK presented evidence in support of summary judgment, including the testimony of Plaintiffs' own expert that all molecules of GSK-manufactured Paxil had been eliminated from Patient's blood at the time she committed suicide and that "the Paxil brand name" did not play any role in Patient's death. Plaintiffs failed to present any evidence to refute GSK's initial burden by connecting a claimed addiction in late 2004 to Patient's suicide in April 2006. Therefore, the district court properly granted summary judgment on this basis.

Plaintiffs also contend that the district court erroneously granted summary judgment on their claim that GSK provided inadequate warnings about the risks of Paxil and Generic Paroxetine. Plaintiffs ask this Court to hold that the duty owed by a name-brand prescription drug manufacturer when providing product warnings extends not only to consumers of its own product, but also to those patients whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug. The crux of Plaintiffs' claims against GSK is that Patient's use of Generic Paroxetine was a cause of her death and could have been avoided had GSK disseminated adequate warnings about the true suicidal risk associated with the use of Paxil and its generic equivalent. GSK responds that the absence of an adequate warning that Paxil can cause suicide is

immaterial because, even if such a warning had been provided by GSK, the undisputed evidence establishes that such a warning would not have changed Dr. Lopez-Colberg's decision to prescribe Paxil or its generic equivalent to Patient. As such, GSK contends that the district court correctly granted summary judgment because Plaintiffs cannot establish the causation element of their warning claims under either a strict liability theory or a negligence theory. *See, e.g.*, *Hines v. St. Joseph's Hosp.*, 86 N.M. 763, 765, 527 P.2d 1075, 1077 (Ct. App. 1974) ("Ordinarily the manufacturer's duty to warn of the dangers of prescription drugs is to the attending physician, not the patient. The physician, in turn, has a duty to disclose dangers to the patient." (citations omitted)).

A plaintiff asserting causes of action based on a failure to warn must prove that, (1) no warning was provided or the warning was inadequate; and (2) the inadequacy or absence of the warning caused the plaintiff's injury. *See Richards v. Upjohn Co.*, 95 N.M. 675, 678, 625 P.2d 1192, 1195 (Ct. App. 1980) ("[Causation] is a factual issue, unless all facts regarding causation are undisputed or, as a matter of law, there is an independent intervening cause."). To satisfy the burden of proving causation in the present case, Plaintiffs must show that adequate warnings would have altered Dr. Lopez-Colberg's decision to treat Patient with Paxil or its generic equivalent. *See id.* (precluding summary judgment in favor of a defendant drug company in a suit arising out of personal injuries suffered by the plaintiff which allegedly resulted from medical treatment by a medication the defendant manufactured, "unless, as a matter of law, (1) [the defendant]'s warnings are adequate, or (2) [the prescribing doctor]'s failure to consult the appropriate literature before prescribing the [medication] constitutes an independent intervening cause"). As such, if it is factually established that Dr. Lopez-Colberg would have prescribed Paxil or Generic Paroxetine to Patient even if GSK had provided a more adequate warning about the risk of suicide, then Plaintiffs cannot prove the causation element of its claims of inadequate warning and GSK is entitled to summary judgment.

Given the undisputed facts of this case—regardless of whether the warnings by GSK were adequate or inadequate—Plaintiffs failed to present evidence to rebut GSK's prima facie showing that the warnings about Paxil's risks did not contribute in any way to Patient's death. While Plaintiffs argue that it is common for prescribing doctors to rely upon a name-brand manufacturer's information when prescribing generic equivalents, they have provided no evidence to rebut the prima facie showing that Dr. Lopez-Colberg did not rely on any representations or warnings provided by GSK when she prescribed Paxil or its generic equivalent to Patient. Indeed, all the prima facie evidence was to the contrary. *See, e.g.*, *id.* at 679-81, 625 P.2d at 1197-99 (concluding summary judgment was improper where a fact issue remained unresolved regarding whether the treating physician's negligent use of a drug remained reasonably foreseeable even if the potentially inadequate warning had been read prior to the improper use of the drug.). During her deposition, Dr. Lopez-Colberg could not recall receiving any literature from GSK regarding Paxil or ever having read the Paxil prescribing information. Instead, Dr. Lopez-Colberg indicated that she most likely selected Paxil or its generic equivalent for Patient simply because it was on Patient's formulary.

Moreover, the evidence established Dr. Lopez-Colberg was actually aware of the risks that Plaintiffs claimed GSK should have made as part of its warning to physicians. Dr. Lopez-Colberg testified in her deposition that she was aware that both Paxil and Generic Paroxetine were accompanied by a "black box" warning for the risk of suicidal thinking and behavior in some patients at the time she prescribed Paxil or its generic equivalent to Patient. Dr. Lopez-Colberg was also aware of the existence of a longstanding concern that antidepressants may play a role in the worsening of depression and the emergence of suicidality in certain patients. However, in Patient's case, Dr. Lopez-Colberg believed that the medical benefits of the drug outweighed the risks. In addition, although the FDA required label changes to the warnings for Paxil and its generic equivalent after Dr. Lopez-Colberg's prescription decision, she explained in her deposition that "[n]othing in the FDA required label changes would affect [her] decision to prescribe Paxil today" to patients who present in the same way that Patient did when Dr. Lopez-Colberg was treating her. Whatever may be said about Dr. Lopez-Colberg's treatment policies and medical decisions, her unequivocal position to use Paxil or its generic equivalent to treat Patient irrespective of the adequacy of GSK's warning label information regarding the risk of suicide precludes Plaintiffs' inadequate warning claims against GSK.

The record establishes that GSK's warnings were not a causation factor in Dr. Lopez-Colberg's decision to treat Patient with Paxil or its generic equivalent. Plaintiffs have failed to provide proof of causation under the theories of liability against GSK that are set forth in their complaint. *See Lent v. Emp't Sec. Comm'n*, 99 N.M. 407, 410-11, 658 P.2d 1134, 1137-38 (Ct. App. 1982) (recognizing that once movants make a prima facie showing of entitlement to summary judgment, the party opposing the motion has the burden of showing there was an issue defeating summary judgment). Because Plaintiffs have failed to present evidence that Dr. Lopez-Colberg would have changed her treatment decision when she prescribed Paxil or its generic equivalent to Patient had a more adequate suicide warning been provided, we conclude that the district court did not err when it granted summary judgment in favor of GSK. *See Glaser v. LeBus*, 2012-NMSC-012, ¶ 12, 276 P.3d 959; *Maralex Res., Inc. v. Gilbreath*, 2003-NMSC-023, ¶ 13, 134 N.M. 308, 76 P.3d 626 ("[A]n appellate court will affirm the district court if it is right for any reason and if affirmance is not unfair to the appellant." (internal quotation marks and citation omitted)). It is, therefore, unnecessary in this case to address Plaintiffs' arguments regarding the adequacy of GSK's product warnings.

Finally, Plaintiffs asserted in their reply brief that the summary judgment decision by the district court did not consider their other liability claims, specifically the remaining claims of negligence and fraud. Although Plaintiffs' brief in chief generally identifies numerous causes of action set forth in the original complaint, no argument or other authority was provided to raise any issue regarding the scope of the summary judgment ruling by the district court. A party is not allowed to raise new issues for the first time in its reply brief. *Alb. Bernalillo Co. Water Utility Authority v. NMPRC*, 2010-NMSC-013, ¶ 59, 148 N.M. 21, 229 P.3d 494 ("It is well established that [our Supreme Court] will not address issues 'raised for the first time in the reply brief.'" (citation omitted)). Under Rule 12-213(C) NMRA, the reply brief "shall reply only to arguments or authorities presented in

the answer brief." Because the scope of the district court's summary judgment ruling was neither raised as an issue in the brief in chief nor presented for review in the answer brief, it will not be addressed any further by this Court. *See In re Estate of Duran*, 2007-NMCA-068, ¶23, 141 N.M. 793, 161 P.3d 290 (noting that this Court will not consider new issues raised for the first time in a reply brief).

CONCLUSION

For the foregoing reasons, we affirm the judgment of the district court.

IT IS SO ORDERED.

TIMOTHY L. GARCIA, Judge

WE CONCUR:

CYNTHIA A. FRY, Judge

LINDA M. VANZI, Judge